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SPECIALTY LABORATORIES ANNUAL REPORT 2001



Like almost every boy growing up along the Massachusetts coast, William Arthur "Candy" Cummings learned how to skip clamshells across the bay. And, like almost every boy, he dreamed of becoming a major league baseball player.

Innovation made his dream come true. Candy knew that if you held a clam shell in a certain way it would trace an arc through the air before skipping across the water. One day he wondered what would happen if he threw a baseball holding it in the same way -- and kept trying until he knew.

In April of 1867, Candy Cummings threw the first curve ball in baseball history. His innovative pitch not only enabled him to make the major leagues, it also earned him a place in Cooperstown, where he was elected to the Baseball Hall of Fame in 1939.

Curious and persistent, Candy would feel right at home at Specialty Laboratories.

A culture of innovation

Specialty's culture of innovation is rooted in our research and development laboratory.

Meeta Patnaik, M.B.B.S. leads the Team of more than 40 doctoral level scientists in our laboratory who have introduced more novel assays in the last 12 years than all other national clinical laboratories combined.



Letter to our shareholders

2001 was a year of accomplishment for Specialty Laboratories. We set ambitious goals and met them despite unprecedented challenges. In our 25 years of leadership in health care, Specialty has demonstrated that profitability and growth are the result of strategic positioning, business innovation and dedicated service.

In 2001, we grew sales to the mid-teens, with revenues increasing more than 14 percent and growth in earnings per share exceeding 20 percent. This performance was achieved by continuing to execute our strategic marketing to hospitals and advancing the resultant long-term shift in our client mix. *Specialty's* focus on growing our share of the estimated \$1.4 billion hospital market for esoteric testing generated a significant annual increase in our hospital business. In 2001, approximately \$100 million, or 56% of total revenue, came from testing performed for hospitals, compared to 51% in 2000. This expansion of our hospital business was a primary driver of revenue for 2001 and we look forward to the prospect of further increases in hospital market share in 2002.

Specialty demonstrated effective cost management and operating efficiency during 2001. During this year, we benefited significantly from laboratory-wide process enhancements and the implementation of additional automation technologies in specimen processing. *Specialty's* pre-analytical sorting system, TARO™, became fully operational in the first quarter of 2001, helping to drive the efficiency gains seen during the year. Later in 2001, we completed the installation of HANA™, our robotic aliquotting or sample-splitting technology, and we expect the system to be fully operational in the second half of 2002. Our main measure of efficiency — the number of patients we serve per day per full-time employee — improved for the third consecutive year, up more than 14% compared to 2000.

Specialty's 2001 financial performance was marked by strong cash flow, providing financial support for our

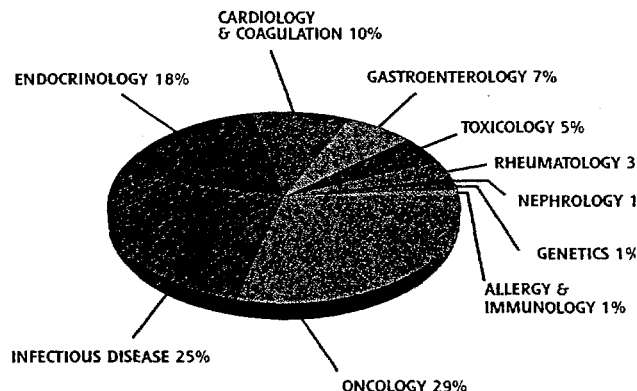
acquisition strategy and other strategic growth programs. We ended 2001 with cash and investments of \$75.1 million, compared to \$75.6 million at the end of 2000. This year-end figure includes cash expenditures totaling more than \$18 million in 2001 for a business acquisition and for the land purchase for our new laboratories. Cash flow from operations generated nearly \$20 million during 2001, allowing *Specialty* to accomplish these strategic purchases while remaining essentially free of debt.

A key to *Specialty's* success is our first-to-market advantage in introducing the latest advances in clinical laboratory medicine. Many of our R&D efforts result in clinically useful tests that merit premium pricing. In 2001, we introduced more than 100 new or enhanced clinical assays for the improved diagnosis and management of disease. In 2002, we will continue to build on our track record of test innovation, selectively deploying research and development resources in the design of novel clinical applications.

We believe our research and development capabilities grant us a unique position in the clinical laboratory industry. To leverage this core internal competence, *Specialty* works closely with many leading pharmaceutical and biotechnology companies to introduce their innovations into clinical laboratory medicine.

Specialty's established distribution channels and expertise in the commercialization of novel assays make us an attractive development partner for companies eager to transform their research discoveries into robust clinical assays with long-term revenue opportunities.

While much is being made of the future potential of this "new science", *Specialty Laboratories* is already utilizing genomic discoveries to create useful, clinical applications that improve patient care -- today. That's what we do. We've been turning the promise of scientific discovery into tools for medical practice for more than 25 years.



Our foundation and heritage

The power of esoteric testing

Our credo "We Help Doctors Help Patients®" is the foundation of who we are and what we do. Based on 2001 revenues, *Specialty* is one of the top five esoteric laboratories in the nation. But, just as important to the physicians who rely on us, we are recognized as the laboratory that provides the tests that help resolve their clinical dilemmas.

From the beginning, *Specialty* focused on creating esoteric assays -- the most technically advanced medical laboratory testing. In contrast to the routine tests and panels performed in most laboratories, esoteric assays require highly skilled personnel and extremely sophisticated instrumentation. Esoteric tests generally command higher reimbursement. These specialized tests provide very specific results that benefit medical decision-making and individual patient management in ways that routine tests generally cannot.

Today, we are a full-service laboratory with more than 3,200 esoteric tests, one of the largest test offerings available from any clinical reference laboratory in the United States. By providing a comprehensive test offering in 10 major medical specialties, we supply cutting-edge assays to physician specialists and also serve as primary provider of referral testing for our hospital and laboratory clients.

Specialty has introduced more novel assays to the medical community in the last 12 years than all the other national clinical laboratories combined. This accomplishment derives in large part from our dynamic research-driven culture. For example, *Specialty* offers the most comprehensive menu of diagnostic and monitoring tools for managing HIV-infected patients. We are the only laboratory to perform the full array of HIV diagnostic confirmation, viral load testing, genotyping, phenotyping and therapeutic drug monitoring as well as a broad range of testing for HIV-related opportunistic infections. *Specialty* also offers a strong menu of tests and services for breast cancer, thyroid disease, systemic lupus erythematosus, congestive heart failure, hepatitis, peptic ulcer disease, pneumonia, cystic fibrosis, and cardiac risk assessment -- to name just a few.

Significant scientific achievements

- 2002** Introduced HIV Phenoscript™; *Specialty* is the first full-service laboratory to perform HIV phenotypic analysis in house
- 2001** Introduced serum HER-2/*neu* testing to identify breast cancer patients more likely to respond to HERCEPTIN® (Trastuzumab)
- 2000** Established pediatric reference ranges for a wide array of endocrine and metabolic testing
- 1999** Developed a flavivirus assay to detect West Nile Fever Virus in response to New York outbreak
- 1998** Enhanced C-Reactive Protein testing to provide the high sensitivity needed to assess cardiac risk
- 1997** Introduced *Helicobacter pylori* Stool Antigen testing to detect the active infection responsible for most peptic ulcers
- 1995** Developed gene sequencing for Hepatitis C Virus GenotypR™ to detect therapeutic resistance
- 1990** Developed the first successful, multi-purpose, semi-automated system for performing enzyme immunoassays
- 1988** First laboratory in the world to be licensed by Cetus to develop PCR testing; introduced HIV DNA testing by PCR
- 1978** Introduced the ANALyzer®, the standard for evaluating systemic lupus erythematosus and related autoimmune diseases



During 2001 we added significantly to our roster of discovery partners, with testing services related to five of these collaborations generating revenue before year-end. In December 2001, *Specialty* teamed up with VIRalliance, a subsidiary of BioAlliance Pharma of France, to introduce Phenoscript™, a proprietary test for predicting resistance to antiviral drug therapy in the treatment of HIV. This test introduction makes *Specialty* the first and only full-service reference laboratory in the United States to perform HIV resistance testing by phenotyping. In 2002, we plan to enter new partnerships, such as those formed recently with Beckman Coulter and Zyomyx, for exploring possible applications of multi-analyte and other emerging technologies to clinical laboratory testing.

Innovation in client connectivity through customized information technology is a *Specialty* hallmark, and in 2001 we continued to build on this core strength. During 2001, we added 57 new CPU-to-CPU installations, providing more of our clients with the benefits of improved efficiency, convenience and turn-around time as well as extending DataPassportMD®, our Web-based ordering and resulting system, to more than 1800 sites.

Drug development testing has been a capability and revenue source at *Specialty* for many years. In 2001, we took steps to strengthen this business segment. These include the hiring of our vice president of clinical trials and the expansion of a sales and marketing group whose sole focus is drug development testing.

We believe that drug development testing forms a natural fit with our business, allowing us to leverage our expertise in the design and performance of robust customized assays.

To support our long-term growth, in 2001 we completed extensive planning of a new centralized laboratory facility. Having purchased a 13.8-acre site in Valencia, California at

the end of 2001, we plan to move our current Santa Monica-based operations into a 195,000 square-foot facility in the second half of 2003. As one of the few large-scale clinical laboratories to be constructed in the United States in the last decade, *Specialty's* new facility will be the first to exploit in its very design the many technological advances of recent years.

Finally, in February 2001 we completed our first major business acquisition with the asset purchase of BBI Clinical Laboratories. Full integration was executed ahead of schedule and the \$9.1 million cash-acquisition was accretive to 2001 results. We believe the acquisition displayed *Specialty's* disciplined approach to selecting strategic opportunities and our ability to integrate complementary acquisitions in the future.

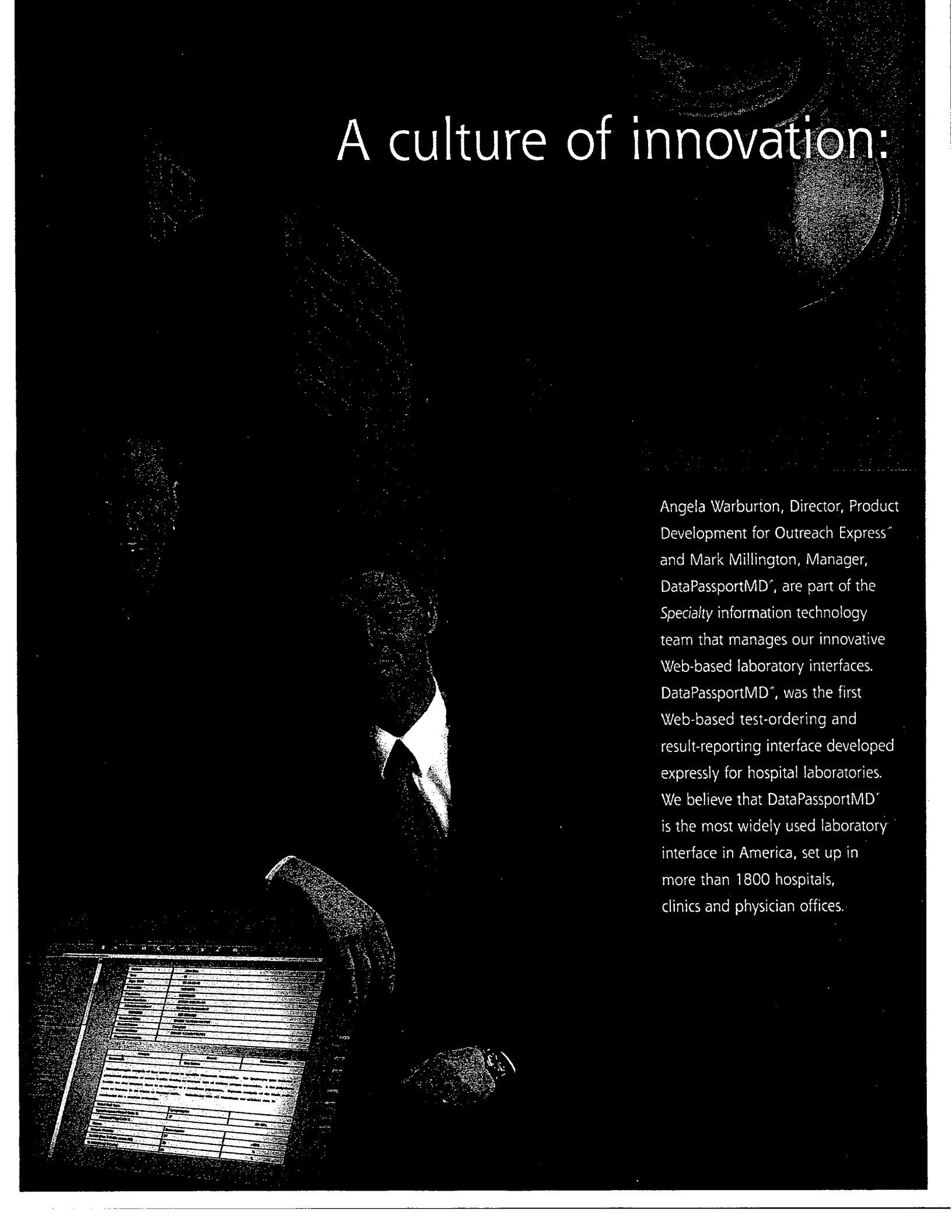
We wish to thank you, our shareholders, for your support. We hope to continue to execute on our business model and justify continued shareholder confidence in *Specialty*.

Back row, L to R: James B. Peter, M.D., Ph.D., Chairman and CEO; Paul F. Beyer, President and COO; Albert Rabinovitch, M.D., Ph.D., Vice President and Chief Medical Officer; Frank J. Spina, Chief Financial Officer

Front row, L to R: Shoji Maruyama, D.M.Sc., Senior Vice President, Engineering; Thomas J. Kosco, Vice President, Business Development; Dan R. Angress, Vice President, Marketing; Meeta Patnaik, M.B.B.S., Assistant Vice President and Director of Research

James B. Peter, M.D., Ph.D.
Chairman and Chief Executive Officer

A culture of innovation:

A high-contrast, black and white photograph of a man in a suit and tie, looking down at a computer monitor. The monitor displays a complex laboratory interface with various forms and data fields. The background is dark and textured, possibly a wall or a large screen.

Angela Warburton, Director, Product Development for Outreach Express™ and Mark Millington, Manager, DataPassportMD™, are part of the Specialty information technology team that manages our innovative Web-based laboratory interfaces. DataPassportMD™, was the first Web-based test-ordering and result-reporting interface developed expressly for hospital laboratories. We believe that DataPassportMD™ is the most widely used laboratory interface in America, set up in more than 1800 hospitals, clinics and physician offices.

Five years ago, Specialty recognized the market opportunity in aligning its business strategy with the hospital community. Our development of innovative, value-added services and processes that directly address the needs of hospitals has provided us with a distinct advantage in serving this market segment.

Science, service and systems

Serving physicians and hospitals

The hospital market for esoteric testing represents, in our view, an important long-term growth opportunity. Specialty has consistently increased its annual share of this \$1.4 billion market during the last four years, from \$34 million in 1997 to \$100 million in 2001. Nearly half of the nation's 5000 hospitals use our services in some capacity and we believe the hospital market will provide us with a strong platform for additional growth.

Hospitals historically have regarded reference laboratories as a necessary cost associated with send-out testing and not as a market partner. Specialty helped change hospitals' expectations by providing many value-added services that were previously unavailable through their reference laboratory. We adhere to a non-compete philosophy and, because Specialty performs only specialized testing, we do not compete with hospitals for the portion of their income derived from performing routine tests. We focus on assays that require instrumentation and/or expertise beyond the scope of most hospital-based laboratories. We provide hospitals with a single, convenient source for all their referral testing and support their efforts to form stronger ties to community physicians through outreach programs.

To support hospitals' efforts to grow their testing business, Specialty introduced Outreach Express®, a Web-based laboratory order-entry system designed to assist hospitals to form closer ties to their affiliated physicians and clinics. With its ease-of-use and minimal capital outlay, Outreach Express® is a powerful connectivity tool for hospitals to maximize and expand their routine testing services.

Our innovation carries over to process improvements that directly benefit our hospital partners. For instance, we initiated a comprehensive plan to improve specimen processing by implementing high-speed robotic systems that have transformed specimen management and will lead to what we believe will be new industry standards in turn-around times and quality.

Service & communication improvements

Introduced HANA™ robotic technology for aliquotting specimens; the HANA™ system will be fully integrated with TARO™, Specialty's automated sorting system for "just in time" delivery of samples for test setup.

Pioneered DataPassportMD®, the first Web-based test-ordering and result-reporting interface developed by and for laboratories. DataPassportMD® is now installed in more than 1800 hospitals, clinics and physician offices.

Provided access to our comprehensive test menu, information on new tests and reference tools for interpretation of tests through our innovative Web site (www.specialtylabs.com).

Enrolled thousands of physicians, laboratorians and other health professionals in Specialty's e-mail notification system to receive updates about testing related to their areas of interest.

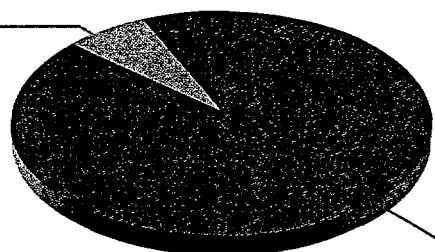
Expanded our courier network for faster, more efficient specimen pick-ups in 350 cities and adjacent communities.

Implemented Automated Call Distribution systems to monitor telephone response time; established and achieved standards for answering 90% of calls within 30 seconds.

PENETRATION OF HOSPITAL LABORATORY BASE

TOTAL MARKET SIZE: APPROX \$1.4 BILLION
IN ANNUAL REFERRAL TESTING FROM HOSPITALS

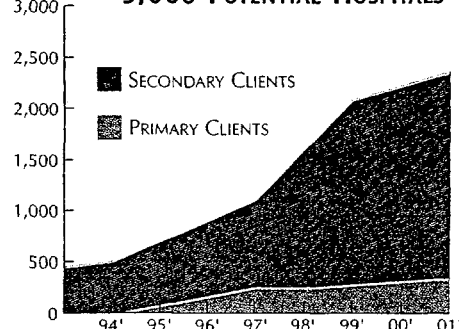
SPECIALTY LABORATORIES
~\$100 MILLION



TOTAL MARKET: ~\$1.4 BILLION

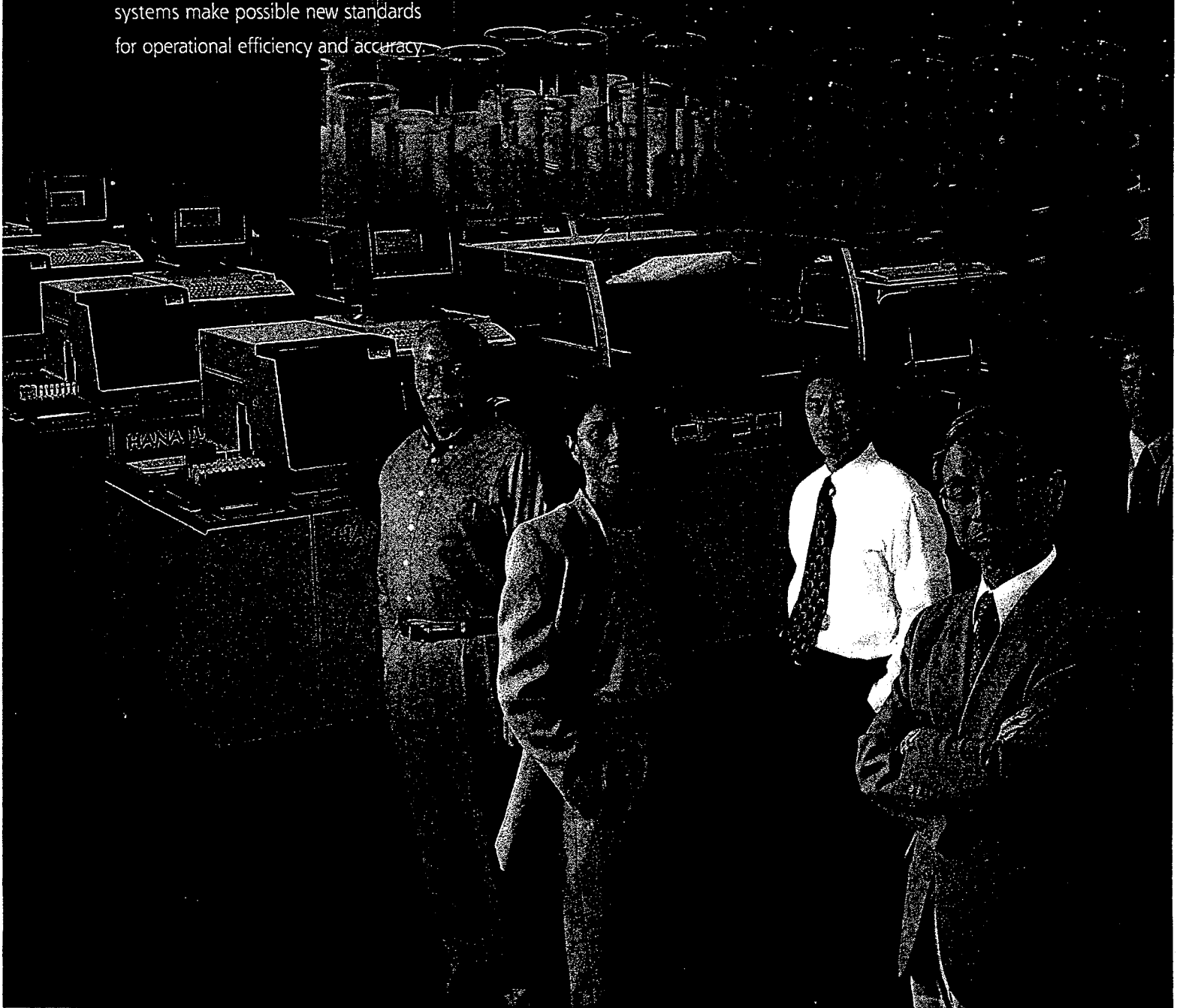
OTHERS

HOSPITALS DOING BUSINESS
WITH SPECIALTY LABORATORIES
~ 5,000 POTENTIAL HOSPITALS



Nowhere is our culture of innovation more evident than in our specimen processing technology. Robert Powell, Assistant Vice President, Logistics; Terry Ximenez, Manager, Specimen Processing; David Tang, Supervisor, Specimen Processing; Shoji Maruyama, D.M.Sc. Senior Vice President, Engineering; Larry Halfhill, Manager, Operations Technology are part of the group that developed our high speed robotic systems for sorting, tracking and aliquotting specimens. These systems make possible new standards for operational efficiency and accuracy.

A culture of innovation:



At Specialty, we see numerous growth opportunities. The now familiar drivers of health care utilization – including the aging of the U.S. population, increased life expectancy, the earlier detection of disease, and improved therapeutic modalities — are likely to spur the demand for esoteric testing.

A center for scientific vision

Partnering to optimize opportunities

Specialty's research focus and 25-year heritage of new assay development position us to take advantage of the changing nature of laboratory medicine ushered in by the molecular revolution in medicine. Our experience in R&D, automation technology, electronic communications, and marketing not only puts us on the cutting-edge of the clinical laboratory industry, but instills in our organization the ability to look forward and adapt swiftly to the needs of our clients and their patients.

The future of medicine suggests drug treatments customized according to the genetic profile of the patient and the disease. The successful application of many future therapies will require clinical laboratory assays to detect specific pathologies, resistance factors and individual pharmacokinetics.

Specialty's strength in customized assay development forms the foundation of our growing drug development testing business. Pharmaceutical and biotechnology companies enlist our services to create the specific assays for drug candidate screening, disease diagnosis, risk assessment and therapeutic monitoring. *Specialty* also provides comprehensive project management and data management services to our pharmaceutical and drug discovery clients to support the complete range of Phase I through Phase IV submissions to the Food and Drug Administration.

Specialty has proven expertise in facilitating the rapid development of commercially viable assays and has partnered with a number of biotechnology research firms to create clinical testing applications based on new technologies and identified gene sequences. Biotechnology and pharmaceutical partners also value *Specialty's* expertise in new test introduction, our national distribution channel and the prospect of near-term revenue. In turn, these partnerships strengthen *Specialty's* pipeline of clinically valuable, premium-priced esoteric assays.

Productive partnerships

Beckman Coulter's Progressive MicroArray platforms and Universal Linker technology for multi-analyte detection and quantitation.

Zyomix's Protein Profiling Biochip™ platform for high throughput protein screening.

Luminex's xMAP™ Technology for multi-analyte detection and quantitation. Three assay panels have been commercialized on this platform to date.

Epoch Biosciences' Minor Groove Binder technology for molecular analysis. Two assays for leukemias have been developed and commercialized using this technology.

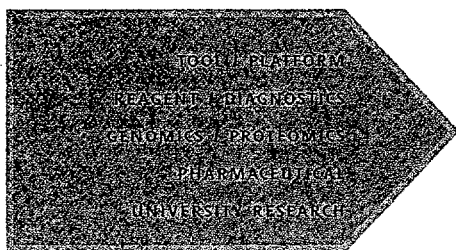
Third Wave Technologies' novel DNA detection system for rapid and accurate detection of SNPs (Invader®). We have successfully commercialized three assay panels with the Invader® platform.

Gen-Probe's patented amplification technology for assaying viruses and bacteria with sensitivity greater than PCR or LCX. We have successfully launched six assays using the Gen-Probe TMA technology.

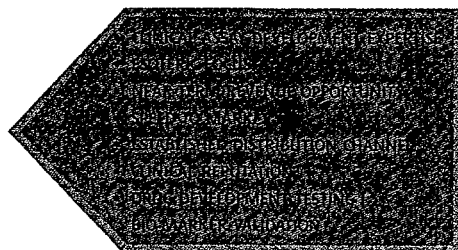
Sequenom's MALDI-TOF mass spectroscopy technology that accelerates the analytical time for high-complexity DNA assays using very small volumes.

PARTNERSHIP OPPORTUNITIES

PARTNER COMPANIES



SPECIALTY LABORATORIES' CONTRIBUTIONS

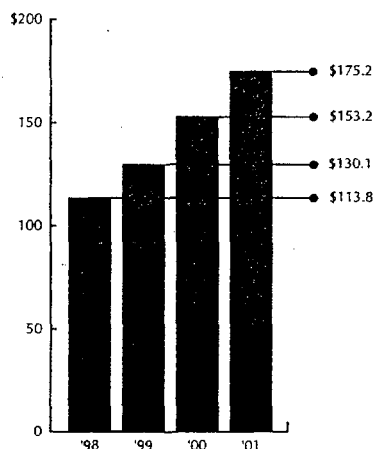


Specialty works with a range of discovery partners to speed the development and commercialization of new clinical assays.

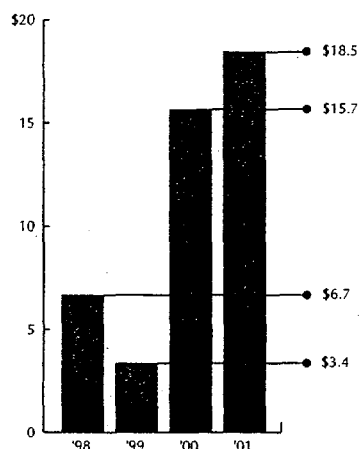
FINANCIAL HIGHLIGHTS

(Dollars in thousands, except per share data)

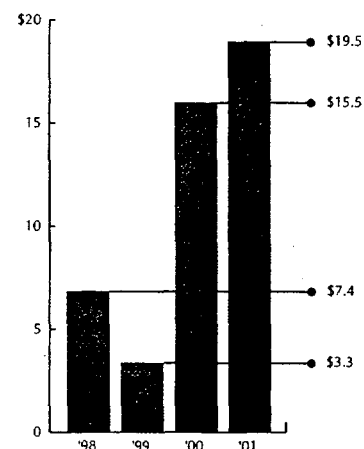
	1998	1999	2000	2001
Net Revenue	\$113,843	\$130,142	\$153,245	\$175,169
Gross Margin	48,745	55,358	66,389	75,214
Operating Income	6,661	3,428	15,669	18,498
Net Income (Loss)	169	(1,142)	8,673	13,079
Income (Loss) per Share - Diluted	0.01	(0.07)	0.49	0.59



NET REVENUE
(in millions)



OPERATING INCOME
(in millions)



**NET CASH PROVIDED
BY CONTINUING
OPERATING ACTIVITIES**
(in millions)

SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995:

This Annual Report contains projections and other forward-looking statements that involve risks and uncertainties. Actual results may differ materially from the results predicted and reported results should not be considered an indication of future performance. Important factors which could cause our actual results to differ materially from those expressed or implied in the forward-looking statements are detailed under "Risk Factors" and elsewhere in filings with the Securities and Exchange Commission made from time to time by Specialty, including our Registration Statement on Form S-1 declared effective on December 7, 2000 (Registration No. 333-45588) and our periodic filings on Forms 10-K, 10-Q and 8-K. Other factors that could cause our actual results to differ materially from those expressed or implied in the forward-looking statements include technological advances enabling our competitors and customers to perform assays similar to ours in a more efficient or cost-effective manner, a general slow-down in the demand for assays due to economic conditions, strategic partnerships which do not yield new assay development, continued consolidation of our industry permitting competitors to gain greater market share and unforeseen failure in our information technology systems disrupting our production capacity and operations, among others. Specialty undertakes no obligation to release publicly any revisions to any forward-looking statements to reflect events or circumstances occurring after the date hereof or to reflect the occurrence of unanticipated events.

CORPORATE HEADQUARTERS

2211 Michigan Avenue
Santa Monica, CA 90404-3900
310-828-6543

SPECIALTY LABORATORIES ON THE INTERNET

www.specialtylabs.com

STOCK TRADING INFORMATION

Specialty Laboratories is listed
on the New York Stock Exchange.
Ticker symbol: SP.

INDEPENDENT PUBLIC ACCOUNTANTS

Ernst & Young, LLP
725 South Figueroa Street
Los Angeles, CA 90017

ANNUAL MEETING

The Annual Meeting of Shareholders
of Specialty Laboratories will be held
on Thursday, May 9, 2002, 8:00 am
Pacific Time at the DoubleTree Guest
Suites Santa Monica, 1707 4th Street,
Santa Monica, CA.

TRANSFER AGENT

Registrar and Transfer Company
10 Commerce Drive
Cranford, NJ 07016-3572
(800) 368-5948
www.rtc.com

FORM 10-K

A copy of the Company's Annual Report
on Form 10-K, as filed with the Securities
and Exchange Commission, is available
through the Company's Web site at
www.specialtylabs.com or without
charge by contacting the Company.

TRADEMARKS

The following are registered and
unregistered trademarks of Specialty
Laboratories: We Help Doctors Help
Patients[®], ANALYZER[™], DataPassportMD[®],
Phenoscript[™], GenotypR[™], Outreach
Express[™], TARO[™], and HANA[™].

*Invader[®] is a registered trademark of
Third Wave Technologies, Inc. Protein
Profiling Biochip[™] is a trademark of
Zyomyx, Inc. xMap[™] is a trademark of
Luminex Corporation. Herceptin[®] is a
registered trademark of Genentech Inc.*

C O R P O R A T E D I R E C T O R Y

BOARD OF DIRECTORS

James B. Peter, M.D., Ph.D.
*Chairman
Chief Executive Officer
Specialty Laboratories*

Paul F. Beyer
*Director
President & Chief Operating Officer
Specialty Laboratories*

Richard E. Belluzzo
*Director
President & Chief Operating Officer
Microsoft Corporation*

Nancy-Ann DeParle
*Director
Health Care Regulatory & Policy Consultant*

Deborah A. Estes
Director & Secretary

Douglas S. Harrington, M.D.
*Director
Chief Executive Officer
ChromaVision Medical Systems*

John C. Kane
*Director
President & Chief Operating Officer (retired)
Cardinal Health*

William J. Nydam
*Director
Chief Executive Officer
Pulse Metric*

Thomas R. Testman
*Director
Managing Partner (retired)
Ernst & Young*

EXECUTIVE OFFICERS

James B. Peter, M.D., Ph.D.
Chief Executive Officer

Paul F. Beyer
President & Chief Operating Officer

Frank J. Spina
Chief Financial Officer

Shoji Maruyama, D.M.Sc.
Senior Vice President, Engineering

Dan R. Angress
Vice President, Marketing

Thomas J. Kosco
Vice President, Business Development

Thomas E. England, Ph.D.
Vice President, Laboratory Operations

Albert Rabinovitch, M.D., Ph.D.
*Vice President, Chief Medical Officer &
Laboratory Director*

Robert M. Harman
Vice President & Chief Information Officer

Specialty Laboratories
2211 Michigan Avenue
Santa Monica, California 90404-3900
310-828-6543 • 800-421-7110 • FAX 310-828-6634
www.specialtylabs.com

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15
OF THE SECURITIES EXCHANGE ACT OF 1934

(MARK ONE)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2001

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-16217

SPECIALTY LABORATORIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

California
(State or Other Jurisdiction
of Incorporation or Organization)

95-2961036
(IRS Employer Identification No.)

2211 Michigan Avenue
Santa Monica, California 90404
(Address of principal executive offices, including zip code)

Registrant's Telephone Number, Including Area Code: (310) 828-6543

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, no par value	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by a check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

As of February 28, 2002 the approximate aggregate market value of voting stock held by non-affiliates of the registrant was \$151,627,754 (based upon the closing price for shares of the registrant's Common Stock as reported by the New York Stock Exchange on that date). Shares of Common Stock held by each officer, director, and holder of 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 28, 2002, there were approximately 21,507,059 shares of Common Stock outstanding.

Documents Incorporated By Reference

Part III incorporates certain information by reference from the registrant's definitive proxy statement (the "Proxy Statement") for the Annual Meeting of Shareholders scheduled to be held on May 9, 2002.

SPECIALTY LABORATORIES, INC.
FORM 10-K ANNUAL REPORT
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This Annual Report on Form 10-K, including information incorporated herein by reference, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements relate to expectations concerning matters that are not historical facts. Words such as "projects," "believes," "anticipates," "will," "estimate," "plans," "expects," "intends," and similar words and expressions are intended to identify forward-looking statements. Although we believe that such forward-looking statements are reasonable, we cannot assure you that such expectations will prove to be correct. Important language regarding factors which could cause actual results to differ materially from such expectations are disclosed in this Annual Report, including without limitation under the caption "Risk Factors" beginning on page 21 of this Annual Report, and in filings with the Securities and Exchange Commission ("SEC") made from time to time by Specialty Laboratories, including our Registration Statement on Form S-1 declared effective on December 7, 2000, our most recent Annual Report and other periodic filings on Form 10-Q and Form 8-K. All forward-looking statements attributable to Specialty Laboratories are expressly qualified in their entirety by such language. We do not undertake any obligation to update any forward-looking statements.

PART I.

ITEM 1. BUSINESS

Overview

Specialty Laboratories is a leading research-based clinical laboratory predominantly focused on developing and performing esoteric clinical laboratory tests, which we refer to as assays. We believe we offer the most comprehensive menu of esoteric assays in the industry, many of which have been developed through our internal research and development efforts. Esoteric assays are complex, comprehensive or unique tests used to diagnose, evaluate and monitor patients. These assays are often performed on sophisticated instruments by highly skilled personnel and are therefore offered by a limited number of clinical laboratories.

Our primary customers are hospitals, independent clinical laboratories and physicians. We have aligned our interests with those of hospitals, our fastest growing client segment, by not competing in the routine test market that provides them with a valuable source of revenue. We educate physicians on the clinical value of our assays through our information-oriented marketing campaigns. Our technical, experienced sales force concentrates on the hospitals and independent laboratories that serve as distribution channels for physician assay orders. We use our advanced information technology solutions to accelerate and automate electronic assay ordering and results reporting with these customers.

We are a California corporation and were incorporated in 1975 under the name Clinical Immunologies, Inc. In 1985 we changed our name to Specialty Laboratories, Inc. Our principal offices are located at 2211 Michigan Avenue, Santa Monica, California 90404.

Clinical Laboratory Industry

Clinical laboratory testing is critical to the delivery of quality healthcare to patients. Laboratory tests are used by physicians to assist in the detection, diagnosis, evaluation, monitoring and treatment of diseases and other medical conditions through the measurement and analysis of chemical and cellular components in blood and other bodily fluids and tissues. Clinical laboratory tests are frequently ordered as part of physician office visits and hospital admissions. Most clinical laboratory tests ordered are considered routine and can be performed by most clinical laboratories. Esoteric assays generally require more sophisticated instruments and highly skilled personnel, and are typically outsourced to independent clinical laboratories that specialize in such assays.

Routine Segment of Clinical Laboratory Industry

Routine tests are ordered by physicians and may be performed by clinical laboratories through the use of standardized prepared kits manufactured by diagnostic companies. Routine tests include procedures in the areas of blood chemistry, hematology, urine chemistry, bacteriology, tissue pathology and cytology. Commonly ordered individual routine tests include red and white blood cell counts, Pap smears, blood cholesterol level tests, urinalyses and pregnancy tests. Because routine tests often employ mass-produced commercial kits, which can be performed with limited training, they are usually more competitively priced than esoteric assays. Although we can perform routine tests, we do not compete in the routine segment of the clinical laboratory industry.

Esoteric Segment of Clinical Laboratory Industry

Esoteric assays are typically ordered when a physician requires additional information to complete a diagnosis, establish a prognosis or to choose and monitor a therapeutic regimen. Esoteric assays include procedures in the areas of molecular diagnostics, protein chemistry, cellular immunology and advanced microbiology. Commonly ordered esoteric assays include viral and bacterial detection assays, drug therapy monitoring assays, autoimmune panels and complex cancer evaluations. In contrast to routine tests, esoteric assays generally require sophisticated instruments and materials and highly skilled personnel to perform and analyze results. Consequently, esoteric assays are generally priced substantially higher than routine tests. Because it is not cost-effective for most hospitals, independent laboratories or physician office laboratories to develop and perform a broad menu of esoteric assays, these assays are generally outsourced to independent clinical laboratories that specialize in performing these complex assays.

Our Competitive Advantages

Comprehensive Menu of Esoteric Assays

We currently offer a comprehensive menu of more than 3,200 esoteric assays, which we believe is greater than any other clinical laboratory in the United States. The breadth of our assay menu distinguishes us from large independent laboratories which typically offer only a select number of esoteric assays and from smaller niche laboratories focused on specific clinical areas. Our comprehensive menu allows our customers to rely on us for substantially all of their esoteric testing needs.

Many of our assays were developed through our R&D efforts and are unique to us. We have historically leveraged our expertise in molecular diagnostics and applied it to high growth segments of the esoteric testing industry including fields of medicine such as infectious disease, gastroenterology, oncology, endocrinology and cardiology. We believe that we have developed one of the most extensive menus of assays in these attractive growth areas.

Beginning in 2000, we broadened our assay development effort and initiated technology partnerships with leading biotechnology companies. Rather than rely solely on internal R&D, we work closely with these companies to incorporate their intellectual property and technological advances into commercially viable clinical applications. We believe that our expertise in assay development and commercialization makes us an excellent partner to biotechnology companies with emerging technologies.

We market and sell many of our esoteric assays under trademarks such as GenotypR™, our assays for predicting resistance to HIV, and ANALyzer®, our assays used to help diagnose complex autoimmune disorders. For the year ended December 31, 2001, more than 45% of our net revenue was derived from branded esoteric assays. We believe these branding efforts have contributed to increased market share and premium pricing as physician specialists often continue to rely on our products, even after the introduction of a similar assay by a competitor.

Research and Development Expertise

We focus our R&D efforts on introducing novel assays, improving existing technologies and enhancing our reputation as an industry leader in new assay development. We have developed and introduced more than 600 new or improved esoteric assays over the past five years and we have the ability to bring a new esoteric assay to market within approximately three months. As an example, in 1988, we believe we were the first commercial laboratory to capitalize on the use of polymerase chain reaction technology, or PCR, by introducing and making PCR tests for HIV widely available. In emergency situations, we endeavor to develop new assays within a shorter period of time. For example, in 1999, within two weeks of learning about the outbreak of West Nile Fever in the New York metropolitan area, we developed a breakthrough detection assay and worked with the Centers for Disease Control and Prevention to notify physicians that this assay was available to monitor the spread of the virus causing the outbreak.

Our R&D expertise also places us in a position to collaborate with biotechnology companies to commercialize their proprietary assays, methods and technologies. For example, in 2001, we signed an agreement with VIRalliance, a subsidiary of BioAlliance Pharma of Paris, France, to perform testing for resistance to HIV therapy using their procedures for phenotyping. With this exclusive technology transfer agreement, we are currently the only full-service reference laboratory in the United States to offer drug resistance testing by phenotyping.

Interests Aligned With Our Hospital Customers

Our predominant focus on the esoteric segment of the clinical laboratory industry allows us to align our interests with those of our hospital customers. Many hospital-based laboratories attempt to increase revenue by marketing and performing routine tests for physicians, commonly known as laboratory "outreach." Hospitals compete with national independent clinical laboratories for these routine tests. We believe that hospitals are more inclined to refer their esoteric testing to independent clinical laboratories that do not compete with them for routine tests.

We enhance our hospital customers' outreach capabilities by marketing our comprehensive menu of esoteric assays as a complement to their routine testing. We also emphasize our laboratory outreach advisory services that help hospitals market their outreach laboratories to their physician community. These advisory services include information technology tools that will help connect hospital laboratories to physician offices. This connectivity improves communications and logistics between the hospital laboratories and their physician clients. We potentially benefit by receiving more esoteric assay referrals from these hospitals as they may receive more routine and esoteric laboratory referrals from their physicians. Ultimately, we believe this strategy enhances our access to esoteric assays that might otherwise be referred to our competitors.

Customer-Focused Information Technology Platforms

We offer all of our customers information technology that accelerates and automates assay ordering and results reporting. We believe that many of our competitors still manage a large portion of their order and results transactions manually. In 1998, approximately 40% of our transactions were transmitted electronically, principally through direct computer-to-computer links with a small number of our largest customers. At that time, we began a customer-focused information technology initiative to efficiently utilize the Internet. This project reduced the implementation time and cost of providing electronic links to large and small customers alike. This led to substantial cost savings, fewer data entry errors, improved ease of assay ordering and shorter turn-around time for results reporting. Today, more than 85% of our transactions with our customers are conducted electronically. Furthermore, we believe that our customer-focused information technology offerings include a number of features that cannot be easily duplicated.

Operating Efficiency and Flexibility

We continually evaluate our operations for process improvement opportunities and have made substantial investments in advanced process automation projects. In the second half of 2000, we began the implementation of our automated specimen management system known as TARO™. This high speed sorting system reduces the potential for human error, increases the productivity of laboratory staff and shortens turn-around time within the laboratory. The TARO™ system became fully operational in the first quarter of 2001 and we believe the TARO™ system boosted our laboratory productivity during the year. As part of our continuing emphasis on productivity improvements, we have developed an ancillary system to TARO™ that is designed for high-throughput, precise division of specimens, a process commonly known as aliquoting. This robotic aliquoting system, designated as HANA™, began pilot operations in the second half of 2001 and is expected to be part of production in second half of 2002.

Our research orientation affords us the flexibility to choose between standardized prepared kits, other available testing technologies, and our own internally developed methodologies depending on cost, quality and market preference. This flexibility provides us the opportunity to gain additional operating efficiencies as we are not solely dependant on platforms designed for specific commercial kits.

Acquisitions

On February 20, 2001, we acquired certain assets and liabilities of BBI Clinical Laboratories, Inc. (BBICL), a Massachusetts corporation, for \$9.5 million in cash. The purchase price was allocated to the assets acquired and liabilities assumed based on the estimated fair values as of the purchase closing date. The acquisition agreement provided for a reduction of the purchase price if certain performance measurements (i.e., asset delivery, client retention and accounts receivable collections) were not achieved. A subsequent evaluation of these performance measurements resulted in the return of \$358,000 by BBICL to us in December 2001. Of the \$9.1 million net purchase price, approximately \$5.9 million was allocated to goodwill and \$1.9 million was allocated to the customer list. The acquisition has been accounted for under the purchase method of accounting. The operating results of BBICL are included in the financial statements from the acquisition date.

Products and Services

We perform all of our testing services at our laboratory facility in Santa Monica, California. We do not have patient service centers and therefore do not obtain specimens directly from patients. Typically, our customers collect a patient's specimen and forward it directly to our laboratory facility. Our laboratory facility accepts specimens 24 hours a day, seven days a week, 365 days a year. Most specimens are analyzed and the results are reported within 48 hours of receipt.

We currently offer what we believe is the most comprehensive menu of esoteric assays in the industry. Following a business evaluation of our testing menu at the end of 2001 and the resultant elimination of certain low-volume services, the menu currently consists of more than 3,200 esoteric assays. The breadth of our assay menu distinguishes us from large independent laboratories that typically offer only a select number of esoteric assays and from smaller niche laboratories focused on specific clinical areas. Our comprehensive menu allows our customers to rely on us for substantially all of their esoteric testing needs. Esoteric assays are typically ordered when a physician requires additional information to complete a diagnosis, establish a prognosis, or to choose and monitor a therapeutic regimen.

Many of our assays were designed by our R&D team and are unique to us. We have historically leveraged our expertise in molecular diagnostics and applied it to high growth segments of the esoteric testing industry including fields of medicine such as infectious disease, gastroenterology, oncology, endocrinology and cardiology. Molecular diagnostic assays comprised approximately 38% of our net

revenue for the year ended December 31, 2001. Broadly speaking, molecular diagnostics includes all test procedures incorporating or identifying DNA- or RNA-based targets. This includes assays detecting the presence of a gene for a given disorder such as cystic fibrosis and assays examining DNA to help predict a patient's response to different drugs, such as HIV resistance assays. These assays can also detect viruses by identifying their unique genetic profile. We believe that we have developed one of the most extensive menus of molecular diagnostics assays. As a result of this expertise, we intend to develop novel, first-to-market assays and capture additional revenues by capitalizing on recent advances in the accumulated knowledge of the human genome.

Our assays for Hepatitis B and C and cardiovascular disease illustrate our ongoing application of advanced diagnostic techniques to diseases affecting a large or growing segment of the population. Hepatitis B and C together affect approximately five million Americans, including three million with active infections. In this market, we offer more than 40 assays using molecular diagnostics and other techniques to help physician specialists diagnose and monitor therapy effectiveness. In the cardiovascular disease market, we offer more than 45 assays designed to help physicians identify high-risk individuals. These assays help identify genetic mutations and infectious, metabolic and autoimmune markers all associated with increased cardiovascular risk.

We market and sell many of our assays under trademarked names such as GenotypR™ and Phenoscript™, our assays for predicting resistance to HIV, and ANalyzer®, our assays used to diagnose complex autoimmune disorders. For the year ended December 31, 2001, more than 45% of our net revenue was derived from branded esoteric assays. We believe these branding efforts have contributed to increased market share and premium pricing as physician specialists often continue to rely on our products, even after the introduction of a similar assay by a competitor.

While we offer more than 3,200 esoteric assays, 30 of our esoteric assays currently account for a substantial portion of our net revenue. These assays, on a net revenue basis, accounted for approximately 45% of our net revenue for the year ended December 31, 2001, and approximately 49% for the year ended December 31, 2000. See "Risk Factors—We rely on a few assays for a significant portion of our net revenue. If demand for these assays were to weaken for any reason, our net revenue would decrease."

Marketing and Sales

Marketing and Sales Organization

Our marketing and sales organization consists of a staff of 14 marketing professionals and more than 60 technical representatives and sales managers. Our sales representatives average more than ten years of selling experience, including seven years in clinical laboratory or diagnostic testing sales. Sales representatives principally focus on large accounts including hospitals or independent laboratories throughout the United States, with a small percentage of their time spent selling directly to physician specialists. Currently five sales representatives focus primarily on clinical trials and drug development testing. We continually educate our sales representatives on the technical and clinical merits of our products. We use traditional sales meetings, technical on-line sales training and in-the-field training to ensure our sales representatives are properly informed about all areas of our product lines and selling processes.

Marketing Strategy

We intend to continue educating physician specialists on the clinical value of our assays through research publications, print advertisement, direct mail, and the Internet. These targeted marketing tools are designed to be effective while minimizing the need for direct physician contact by our sales representatives. We actively pursue publication of our scientific research in peer-reviewed journals and have had more than 800 such articles published. We have printed and continually update ten

widely-used, proprietary reference manuals on the use and interpretation of our assays, focusing on medical specialties such as infectious disease, gastroenterology, oncology and cardiology. We present our research at scientific meetings and we exhibit at more than 70 national and regional conferences throughout the year. Our web site is another vehicle for educating physicians about our assays and contains our entire directory of services, on-line technical materials and links to other medical sites that support the role of esoteric assays in effective diagnosis and treatment of diseases.

Sales Strategy

We concentrate our selling efforts on the management teams of hospitals and other independent laboratories that serve as distribution channels for physician assay orders. These management teams typically include laboratory managers, pathologists, finance and information technology personnel. To a lesser extent, we also call directly on physician specialists who create the demand for our assays.

In connection with our hospital focused strategy, we concentrate on increasing the volume of testing we perform for existing clients. Our goal is to grow the percentage of total testing these existing clients send to us, so that we become their primary provider of esoteric reference testing. Our marketing department provides our sales representatives with a comprehensive database containing pertinent information on hospital information technology systems, key contacts and existing competition. Sales representatives are trained to find new market opportunities and provide solutions to address unmet customer needs which may include outreach support, information technology products, assay information and general servicing.

We also facilitate hospital sales through affiliations with group purchasing organizations. Although hospitals participating in group purchasing organizations are not obligated to use the group purchasing organization contracted laboratory for their reference testing, a group purchasing organization contract may provide us with access to additional hospital business. For further discussion of our group purchasing organization relationships, see "Customers—Hospitals" below.

Customers

Our customers include hospitals, independent laboratories, physician specialists and other medical providers. The following table provides percentages of our net revenue by class of customer:

	Years Ended December 31,		
	1999	2000	2001
Hospitals	46.7%	51.3%	56.0%
Independent Laboratories	36.5%	35.7%	34.0%
Physician Specialists and Others	16.8%	13.0%	10.0%
Total	100.0%	100.0%	100.0%

Hospitals

Hospitals, our fastest growing customer segment, accounted for approximately 56% of our net revenue for the year ended December 31, 2001. Of the estimated more than 5,000 hospitals to which we target our services, approximately 2,300 are currently our customers. We are a primary provider of esoteric reference laboratory testing services for more than 340 of these hospital customers.

Many of our hospital customers are part of group purchasing organizations which typically pool independent hospitals together to negotiate for pricing and services, including prices for laboratory tests. Generally, hospitals participating in group purchasing organizations are not obligated to use the group purchasing organization contracted laboratory for their reference testing and many hospitals are

affiliated with multiple group purchasing organizations. We are currently under contract with the following voluntary group purchasing organizations:

<u>Group Purchasing Organization</u>	<u>Estimated Number of Member Hospitals</u>	<u>Contract Expiration Date</u>
AmeriNet	2,000	May 2004
Health Services Corporation of America	800	July 2004
Novation (formerly known as VHA)	800	April 2004
Shared Services Healthcare	550	June 2003
Managed Healthcare Associates	300	May 2003

Each of our agreements with group purchasing organizations provide for discounted fee structures for our assays including capped price increases. Some of these contracts provide additional discounts for certain assays. Most of these contracts also provide that we pay a quarterly or monthly administrative fee to the group purchasing organization.

Independent Laboratories

For the year ended December 31, 2001, regional independent laboratories represented approximately 20% of our net revenue and national independent laboratories represented approximately 14% of our net revenue. Taking regional and national independent laboratories together, we can service more than 1,300 accounts in the independent laboratory segment. Regional independent laboratories typically receive test requests directly from physicians. Regional laboratories will perform the routine tests and outsource the esoteric assays to an esoteric national laboratory like us. Although other national independent laboratories perform some esoteric testing, they may outsource to us any esoteric assays they are unable to perform and also honor requests from physician specialists who specify that we perform particular assays.

In October 1999, we entered into an agreement with Unilab Corporation pursuant to which it has agreed to refer to us, until the agreement expires in October 2002, at least 90% of the esoteric laboratory services it outsources each year or, in the event of a change of control of Unilab or the purchase by Unilab of a licensed clinical laboratory with a test menu materially broader than that of Unilab, at least \$800,000 of esoteric laboratory services per month. For the year ended December 31, 2001, Unilab represented less than 8% of our net revenues. This agreement can only be terminated for cause and will automatically renew for successive renewal terms of one year each unless terminated by either party.

Physician Specialists and Others

For the year ended December 31, 2001, physician specialists comprised approximately 8% of our net revenue and represented more than 1,200 accounts. Currently, there are more than 200,000 physician specialists in the U.S., of which approximately 120,000 fall directly into our targeted medical specialties. Although they account for a small percentage of direct net revenue, physician specialists can influence the clinical acceptance of an assay, and can specifically influence laboratory choice by specifying that a particular specimen be sent to us or by ordering a particular assay that is unique to or branded by us.

Our remaining net revenue is derived primarily from clinical trials drug development testing. Our clinical trials business focuses primarily on pharmaceutical and biotechnology companies trying to develop new drugs. We offer these companies customized assays to aid in the study and development of new therapeutic agents and applications. Testing services for the drug development market comprised approximately 2% of our net revenue for the year ended December 31, 2001. We believe that many

companies choose us for their drug development testing because of our experience in developing new assays and offering the necessary tools to manage the resulting data.

Payors, Billing & Reimbursement

We typically bill our customers, such as hospitals or other independent laboratories, directly. In some instances, we bill the individual patient directly or third party payors such as Medicare, Medicaid or private insurance. The following table illustrates our payor mix as a percent of net revenue:

	Years Ended December 31,		
	1999	2000	2001
Customer	84.3%	82.6%	82.9%
Patient	8.3%	10.1%	10.2%
Medicare	3.5%	4.0%	3.4%
Medicaid	2.0%	1.5%	1.4%
Other Insurance	1.9%	1.8%	2.1%
Total	100.0%	100.0%	100.0%

All of our billing and payment functions are executed through a centralized computerized billing system. Our web-based DataPassportMD™ product collects required billing information for Medicare, Medicaid and other insurance reimbursements at the time of assay ordering.

Information Technology

We have invested significant resources into proprietary information technology that accelerates and automates test ordering and results reporting with our customers. These information technology products, collectively branded as DataPassport®, are designed to take advantage of new Internet-based technologies. Although some customers only require a simple electronic transfer of orders and results, others are seeking solutions to help them connect disparate systems or connect physician practices associated with laboratory outreach programs. Compared to other currently available information technology applications designed to have similar functionality, we believe all of our information technology products have the advantages of faster system implementation, greater ease of use and lower customer costs. We have also invested resources designed to provide patient confidentiality and compliance with all governmental regulations regarding data privacy and security.

In 1998, approximately 40% of our transactions were transmitted electronically, principally through direct computer to computer links with a small number of our largest customers. At that time, we began a customer-focused information technology initiative to effectively utilize the Internet and provide electronic connectivity to large and small customers alike. Today, more than 85% of the transaction volume with our customers is transmitted electronically.

Our current offering of information technology products include DataPassport® client interface module, DataPassportMD™ and Outreach Express™. We are in the process of optimizing Outreach Express™ described in detail below. We believe that our evolving suite of information technology products will continue to lead to greater customer loyalty, a reduction of data entry errors, acceleration of test ordering and results reporting, and substantial cost savings. The security features on our information technology products are intended to protect the confidentiality of patient information in accordance with state and federal law.

DataPassport® Client Interface Module

Because of the volume of assays ordered, our larger accounts require a direct connection between us and their Laboratory Information System, also known as LIS, to streamline the assay ordering and results reporting process. Traditional methods of connecting directly with a customer's LIS system are

generally cumbersome and require a significant amount of time to implement because such links are dependent on the involvement of a third party LIS vendor to assist in software programming. Our DataPassport® client interface module greatly decreases this implementation lag-time and bypasses the need for the LIS vendor by emulating the hospital's LIS data format. Consequently, our client interface module may be operative within six to eight weeks, as compared with six months or more for traditional computer to computer links. The client interface module also provides additional features not available with traditional computer to computer links, such as assay and physician utilization reports, and a flexible architecture that can accommodate future expansion and require fewer internal customer resources.

DataPassportMD™

We believe this product is the most widely used web-based laboratory order entry and resulting system in hospitals today. Currently, more than 1,200 of our customers are using DataPassportMD™. One of the key benefits of DataPassportMD™ is that it permits electronic order entry and results reporting for our smaller volume customers, and can be used alone or as part of a flexible architecture. DataPassportMD™ does not require any specialized hardware at the user site, making implementation almost immediate. We have added unique features to enhance the order entry and results reporting screens, including on-line access to our proprietary "use and interpretation of tests" books, graphical reporting features and extensive report generation tools for monitoring test or customer usage. We believe this product is user friendly, requiring only simple training for system users and on-site data maintenance.

Outreach Express™

We anticipate that our hospital and independent laboratory customers wishing to grow their testing business will use Outreach Express™. This product is intended to allow these customers to connect with physicians directly over the Internet. Outreach Express™ uses the functionality of DataPassportMD™ and is hosted through our servers. The advantages to these customers are that no specialized hardware must be purchased and the entire information technology product can be supported outside their laboratory. We designed Outreach Express™ to enable physicians to access assay results from hospitals and independent laboratories electronically and, thus, more quickly than receiving such information manually. We believe that Outreach Express™ provides these customers with a competitive advantage in their respective market. By aiding these customers in their outreach efforts, we believe that they will continue to utilize our services. We currently have Outreach Express™ in testing at thirteen pilot sites.

Process Automation

We have implemented an automation system known as the Total Accessioning Re-Organization system, or TARO™, for our pre- and post-analytical specimen management. This high speed automated sorting system reduces the potential for human error, increases the productivity of laboratory staff and decreases overall turn-around time within the laboratory. We began implementation of TARO™ in the second half of 2000 and it became fully operational in the first quarter of 2001. Specifically, TARO™ automates specimen sorting to the appropriate assay batch, enhances specimen tracking applications and reduces manual set up procedures at the analytical workbench.

As part of our continuing emphasis on productivity improvements, we are currently developing an ancillary system to TARO™ that is designed for high-throughput, precise aliquoting. This automated system, designated as HANA™, is expected to substantially reduce the traditional manual process of dividing specimens into smaller components when multiple tests are requested on a single patient. Like TARO™, this system is expected to deliver higher quality service levels to our customers while at the same time improve our operating efficiencies. This system began pilot operations in the second half of 2001 and is expected to be part of production in the second half of 2002.

We utilize information technology applications extensively in conjunction with automated specimen management systems at the analytical site within the laboratory. We will continue to explore other projects to enhance our processes for improved accuracy and productivity.

Research and Development

We focus our R&D efforts on accelerating new assay development, evaluating alternatives to costly diagnostics, improving existing assay performance and commercializing existing technologies developed by our strategic partners. All of our R&D efforts have been company-sponsored. No R&D efforts have been sponsored by our customers. R&D spending has averaged \$2.2 million per year since 1999. Through our efforts, we have introduced more than 600 new or improved esoteric assays in the past five years. Our R&D efforts enable us to grow revenues, increase market share and command premium pricing for many of our assays.

Our process of creating a new assay begins with input from many sources, including our scientific team, our marketing department, scientific symposiums, customers, and scientific journals. A team composed of representatives from R&D, marketing and operations evaluates the potential for a proposed assay, examining issues from disease prevalence to production costs. Once an assay is approved by this team, our R&D staff initiates development and validation of that assay. Currently, our average time to internally develop and market a new esoteric assay is three months.

To advance our internal development efforts of new technology applications, we seek strategic partners whose technology can be applied to a variety of disease conditions and produce advantages related to accuracy, performance, speed of testing or cost reduction. Our adoption of the Minor Groove Binder reagent from Epoch Biosciences is an example of such an enabling partnership. By incorporating this reagent into our test for Chronic Myelogenous Leukemia (CML), we were able to increase the sensitivity of the test by a factor of 500. This improvement affords a major clinical advantage to physicians monitoring the therapeutic response of their CML patients.

Strategic Partnerships and Licensing Arrangements

We actively pursue strategic partnerships with the developers of both new diagnostic assays and new platform and process technologies that accelerate assay development and commercialization. Such relationships allow us to expand our range of offered services, reduce our costs and increase the accuracy of performing assays. In addition, some of these agreements provide us with the opportunity to collect royalties from diagnostic product manufacturers for assays that we commercialize using such technologies.

New Assay Technologies

During 2001 we licensed intellectual property that has enabled us to commercialize several new assays. Among them are Phenoscript™, an HIV phenotyping assay that we licensed from VIRalliance, a subsidiary of Paris-based BioAlliance Pharma, and COL1-A1, a genetic marker for predisposition to osteoporosis that we licensed from Axis-Shield. We anticipate that licensing new-assay intellectual property will be increasingly important in the future.

Platform and Process Technologies

We have a large and growing number of diagnostic platform and process technology partners, including:

- Beckman Coulter's Progressive MicroArray™ platforms and Universal Linkers™ technology for multi-analyte detection and quantitation.
- Zyomyx' Protein Profiling Biochip™ platform for high throughput protein screening.

- Luminex' xMAP™ Technology for multi-analyte detection and quantitation. Three assay panels (each panel has from 12-4 analytes in it) have been commercialized on this platform to date.
- Epoch Biosciences' technology which improves performance of assay systems for molecular analysis that is used to monitor therapeutic response in patients with cancer. Two such assays for leukemias have been developed and commercialized.
- Third Wave Technologies' novel DNA detection system for rapid and accurate detection of SNP's. We have successfully commercialized three assays with the Invader technology.
- Gen Probe's patented TMA technology for assaying for viruses and bacteria with sensitivity greater than PCR or LCX. We have successfully launched six assays using the Genprobe technology.
- Sequenom's MALDI-TOF™ technology which allows us to significantly accelerate the analytical time for high complexity DNA assays using very small reaction volumes.

Proprietary Rights

We protect the proprietary methodologies for assays developed by our R&D group as our trade secrets. All of our employees and consultants sign a proprietary information and inventions agreement upon hiring. To date, we have experienced no known material theft of trade secrets. We have copyrighted the proprietary software developed for products such as DataPassport®, DataPassportMD™, Outreach Express™ and TARO™. We also have obtained copyright registrations, as appropriate, for our published books and clinical information which we provide either electronically or in print to requesting clinicians. Many of our assays are branded products and we have applied for trademark registrations accordingly. We also have registered marks used in our clinical information and other advertising materials.

In April 2000 and June 2001, we received letters from the National Institutes of Health, the NIH, advising us that it believes that two of our assays, HIV-1 GenotypR™ and HIV GenotypR-PLUS™, infringe its U.S. Patent 5,252,477. The patent is generally directed to the human HIV protease amino acid and DNA sequences and methods for synthesis and purification.

We received a letter from Chiron Corporation in or about February 1998 claiming that some of our Hepatitis C, or HCV, assays may be covered by its U.S. Patent 5,714,596. As of June 23, 2000, we entered into an agreement to purchase the majority of our HCV assays from Bayer Corporation, which has represented that it has a license for U.S. Patent 5,714,596.

Neither NIH nor Chiron has filed suit against us. We intend to defend any such suit that may arise vigorously and to assert all available defenses to allegations of patent infringement that would be available to us. We do not believe the outcome of either of these matters is likely to have a materially adverse effect on our business, financial condition, results of operations, or cash flows.

Competition

The esoteric clinical laboratory business is highly competitive and is dominated by several national laboratories, as well as many smaller niche and regional organizations. Our primary competitors include large independent laboratories, such as Quest Diagnostics and Laboratory Corporation of America Holdings, or LabCorp, that offer a wide test and product menu on a national scale. These large national independent laboratories have significantly greater financial, sales and logistical resources than we do and may be able to achieve greater economies of scale, or establish contracts with payor groups on more favorable terms than we can. We also compete with smaller niche laboratories, like Impath or Athena Diagnostics, that occupy a narrow segment of the esoteric market by offering a very specific assay menu. Finally, institutions such as Mayo Medical Laboratories and Associated Regional

University Pathologists that are affiliated with large medical centers or universities generally lack the advantages of the larger commercial laboratories but, instead compete with us on the limited basis of offering a perceived higher quality.

We believe that healthcare providers consider the following factors, among others, in selecting an esoteric clinical laboratory:

- accuracy, timeliness and consistency in reporting assay results;
- number and types of assays performed by the laboratory;
- ability to develop new and useful assays;
- service capability and quality;
- ability to transfer assay results electronically;
- reputation in the medical community;
- pricing of assay services; and
- reputation as a source of clinically useful, assay-related information.

We believe that we compete favorably with our principal competitors for esoteric testing services in these areas. However, we cannot assure you that we will maintain our competitive position in the future.

Quality Improvement

We maintain a comprehensive quality improvement program that monitors and evaluates performance to ensure accuracy and precision in pre-analytical, analytical, and post-analytical processes of clinical laboratory testing. The processes are documented with policies and procedures that are based upon nationally standardized guidelines on test performance and results interpretation. This also includes the routine monitoring of control results, and blind specimen submissions to assess accuracy and reproducibility. We believe that we have obtained all appropriate approvals and licenses for providing clinical laboratory testing services. We participate in numerous quality and proficiency testing programs, including the proficiency programs administered by the College of American Pathologists and other state, national and international programs. In addition, the laboratory participates in the College of American Pathologists Laboratory Accreditation Program which requires inspection by outside experts and self-evaluation.

All laboratory testing and associated processes are described in written policies, procedures and validations under electronic document control. These documents include instructions for routine monitoring of quality control data, tolerance limits, and corrective actions taken if tolerance limits are exceeded.

Government Regulation

Antifraud Laws/Overpayments

Numerous federal and state laws provide for penalties in connection with improper billing practices involving healthcare services. Remedies under these laws include imprisonment, monetary penalties, damages and asset forfeitures. Monetary penalties may reach \$10,000 for each test improperly billed. These laws include, among others, the federal False Claims Act, which prohibits the submission of fraudulent claims in connection with Medicare, Medicaid and certain other governmental programs. In addition to direct suits by the federal government, the False Claims Act authorizes private parties to bring suit on behalf of the government against providers and entitles such a person to a portion of any final recovery. In addition, the Social Security Act provides for civil monetary penalties and recovery of

treble damages for services which are fraudulently billed to the Medicare program or a Medicaid program. Providers convicted of any criminal offense relating to Medicare or Medicaid covered services or of certain felonies in connection with other private or governmental healthcare programs are subject to mandatory exclusion from the Medicare and Medicaid programs. In addition, the federal Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration or HCFA) may exclude from the Medicare and Medicaid programs any provider convicted under any state or federal law of certain offenses relating to fraud, or who has been subjected to a civil monetary penalty under the above-described provisions of the Social Security Act. CMS also may suspend Medicare payments to any provider it believes has engaged in fraudulent billing practices. Remedies generally similar to those described above are also available to state Medicaid programs, and California law also denies Medi-Cal enrollment to any provider that has entered into a settlement in lieu of conviction for fraud or abuse in any government program and further provides that a provider that is under investigation by certain government agencies for fraud or abuse shall be subject to temporary suspension from the Medi-Cal program.

The federal government has investigated and continues to investigate the billing practices of numerous large and small clinical laboratories. Such investigations and related litigation have involved a broad range of issues, including the practices of laboratories of grouping tests into panels for billing and ordering purposes, the marketing of tests to physicians, billing for hematology tests and indices, billing for tests not performed, double billing, billing for tests which are not medically necessary, improper coding, and numerous other potentially improper practices. These investigations have resulted in all of the largest national independent laboratory companies, as well as many regional and local laboratories, having entered into settlement agreements in amounts that in several instances have exceeded \$100 million. While most fraud enforcement activity has involved the Medicare and Medicaid programs, lawsuits by private insurance companies based upon fraud theories are also common. To our knowledge, we are not subject to any investigations or lawsuits alleging fraudulent billing practices. However, there can be no assurance that our activities will not be challenged under the fraud laws in the future.

Independent of fraud allegations, Medicare and Medicaid programs and private payors may retroactively determine that certain payments for services must be repaid due to a failure to satisfy applicable payor requirements. Significant delays in or recoupments of payments could have a material adverse effect on our revenues.

Laboratory/Physician/Hospital Relationships

“Self-Referral” Legislation. We are subject to “self-referral” prohibitions under federal Medicare law, commonly known as the Stark Law and to similar restrictions of California law, the Physician Ownership and Referral Act, which apply to referrals by California physicians. When taken together, these restrictions generally prohibit us from billing the patient or any governmental or private payor for any test when the physician ordering the test, or any relative of such physician, has an investment interest in, or compensation arrangement with us.

Both the Physician Ownership and Referral Act and the Stark Law contain an exception for referrals made by physicians who hold investment interests in a publicly traded company that has shareholders’ equity of \$75 million at the end of its most recent fiscal year, and satisfies certain other requirements. California’s self-referral restrictions applicable to referrals of workers’ compensation testing also contain a similar exception, except that this exemption requires that total gross assets at the end of the laboratory’s most recent fiscal year has to be at least \$100 million. At our fiscal years ended December 31, 2001 and 2000, our shareholders’ equity and total assets exceeded \$100 million, and we are therefore now entitled to the benefit of the public company exemptions. However, the public company exemptions most likely were not available to us prior to January 1, 2000. Because many of our shareholders hold stock in the name of their stock brokerage firm, it may not have been possible

for us to fully comply with the self-referral requirements prior to our qualifying for the public company exemptions. Despite the public company exemptions, we will need to monitor our compensation relationships with physicians under the self-referral laws on an on-going basis. For example, our provision of information technology support to physician customers must be carefully structured in order to comply with the self-referral laws. Laboratories which violate the Stark Law must refund any amounts collected in connection with prohibited referrals and are also subject to monetary penalties of \$15,000 for each test improperly billed for and exclusion from the Medicare and Medicaid programs. In addition, billings for services where the referral was prohibited may be actionable under false claims statutes. Substantial penalties may also be imposed in the event of Physician Ownership and Referral Act violations. Although we believe that we are in compliance in all material respects with the Physician Ownership and Referral Act and the Stark Law, there can be no assurance that we will not be found to be in violation of these laws in the future. In addition, other states have self-referral restrictions with which we may have to comply that may differ from those imposed by federal and California law.

Regulations implementing and interpreting certain provisions of the Stark Law were released by CMS on January 4, 2001, with an effective date of January 4, 2002. The most substantial provisions of the new regulations address the provision of services by physicians in their offices and define the services, other than laboratory services, to which the Stark Law applies. Provisions contained in the new regulations which define the types of indirect compensation relationships to which the Stark Law applies and which create new exceptions for certain types of financial relationships may have some relevance to us. In addition, the new regulations interpret an exception under the Stark Law which allows laboratories to provide physicians with supplies used solely to collect, transport, process or store specimens. CMS believes this exception is limited to items of low value, such as single use needles, vials and specimen cups, and that biopsy needles, and similar items such as snares, reusable aspiration and injection needles and sterile gloves, do not function solely as specimen collection devices, and therefore trigger the self-referral restrictions if they are provided without a fair market value charge. However, California's self-referral restrictions contain no exemption which would allow such items to be sold to physicians, even at fair market value, and a laboratory complying with CMS new interpretations may be required to have its California physician customers obtain the restricted types of supplies from third parties. The new interpretations also acknowledge that the provision of a phlebotomist without charge is permitted so long as the phlebotomist performs solely laboratory functions for the laboratory providing the phlebotomist complying with these new CMS interpretations may result in cost-savings for laboratories. Nevertheless, because the prior regulations largely implemented the Stark Law as it applies to clinical laboratory services, we do not believe that the new regulations will have any material impact on us.

Antikickback Laws. The federal Medicare/Medicaid antikickback statute prohibits laboratories from paying remuneration as inducement for referrals of patients or specimens for testing paid for by the Medicare or Medicaid programs. Based upon a federal court decision specifically considering physician ownership of laboratories and an antikickback safe harbor regulation applicable to investments in certain publicly traded companies, we believe that a challenge to physician investments in our company is unlikely.

A number of business practices in the clinical laboratory industry have been criticized by Medicare's Office of Inspector General, including the provision of phlebotomy staff to clients who perform clerical or other functions for the client which are not directly and solely related to the collection or processing of laboratory specimens, the provision of computers or fax machines to clients which are not used exclusively in connection with performance of the laboratory's work, the lease of space in a physician's office for rent which exceeds the fair rental value of such space, certain acquisition agreements where the sellers may make referrals to the buyer after the sale and other compensation relationships between laboratories and entities from which they receive referrals, or to

which they make referrals, if such relationships are intended to induce referrals. In addition, Medicare's Office of Inspector General has indicated that discounts given by laboratories to clients with respect to their private pay patients and/or HMO patients must not be intended to induce referrals of Medicare or Medicaid patients by the client to the laboratory. Our business practices are governed by the antikickback laws, including our negotiated discounted pricing arrangements, our participation in group purchasing organizations and provision of information technology to our customers. Because, in most instances, we bill our customers for both their Medicare and non-Medicare testing at a uniform price, we believe the Office of Inspector General's concerns regarding discounts will not apply to us. Moreover, statutory exceptions and "safe harbor" regulations are available to protect certain discounts offered to customers and certain payments we make to group purchasing organizations.

Many states, including California, also prohibit payments from being given to physicians, hospitals or others by clinical laboratories as compensation or inducement for referrals of patients or test specimens, regardless of the source of payment for such testing. In addition, laboratories offering pricing to their customers that is more favorable than that offered directly to patients may be deemed to pay prohibited kickbacks under state laws. However, we believe that a kickback will not result under California law if the laboratory's customer passes all of such discount to its patients in the form of lower testing charges. Because we expect our California customers to comply with the "pass through" requirements applicable to them, we do not believe that any favorable pricing we offer to California physicians or hospitals violates California's antikickback laws. However, it is possible that markups by our non-California customers who are not bound by anti-markup restrictions may implicate California's antikickback laws.

Any action taken against us under the Medicare/Medicaid antikickback statute could result in criminal penalties being imposed pursuant to the U.S. Sentencing Guidelines, civil monetary penalties of \$50,000 per violation plus treble damages, and exclusion from Medicare and Medicaid participation. Laboratories that violate the California antikickback laws or similar antikickback, anti-markup, or direct billing laws of other states may be subject to loss of licensure and substantial fines.

While we believe that we are in compliance with the antikickback statutes, there can be no assurance that our relationships with physicians, hospitals and other customers will not be subject to investigation or a successful challenge under such laws. If imposed for any reason, sanctions under the antikickback laws could have a material adverse effect on our business.

Certification and Licenses

We are required to maintain various federal and state licenses, certifications and permits. Our laboratory is certified pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), which subject human clinical laboratories to national standards. Because of the location of our laboratory in Santa Monica, licensure is also required under the laws of the State of California. Since we perform patient testing from all states, we hold licenses in additional states including Florida, Maryland, New York, Pennsylvania, Ohio, West Virginia, and Rhode Island. Our laboratory is also accredited with distinction by the College of American Pathologists, a private accrediting agency that has deemed status under CLIA-88.

The above agencies have established requirements and detailed specifications for the day-to-day operation of a clinical laboratory. Some of these elements include: training, education, and competency of testing and supervisory personnel; design and implementation of a scientific quality control program; documents that fully characterize method performance (validations) and execution (procedures); and a comprehensive quality improvement program. In addition, federal law mandates performance in a graded and CLIA-approved proficiency testing program. This involves testing of unknown specimens that have been specifically prepared for the laboratory to evaluate national interlaboratory performance. If a laboratory is out of compliance with CLIA-88 or other applicable requirements, the

federal Centers for Medicare and Medicaid Services (CMS) and/or the California Department of Health Services (CDHS) may assess substantial civil money penalties, restrict tests that the laboratory may perform, impose specific corrective action plans, suspend the laboratory's approval to receive Medicare payments, and/or suspend, revoke or limit the laboratory's CLIA-88 or state license. If a laboratory's CLIA-88 certificate or state license is suspended or revoked, its ability to perform further testing is terminated, and there may be denial of payments previously made by Medicare and/or Medicaid. Sanctions imposed by individual states may restrict testing for residents of that state.

In June 1999, CMS informed us that we were not in compliance with CLIA-88 regulations pertaining to specific quality assurance functions, and imposed certain fines in connection therewith. After CMS resurvey in June 2000, we were able to satisfy them that we were in compliance with the applicable requirements. We appealed the fine imposed by CMS, and subsequently settled the matter by paying CMS the sum of \$87,400.

In June and October, 2001, we underwent unannounced inspections by CDHS representing both the State of California and acting as agent of CMS under CLIA-88. As a result, we were cited by CDHS with 20 deficiencies under California law and CLIA-88. A separate statement indicating 12 overlapping deficiencies under CLIA-88 was issued by CMS in February 2002 based upon the same inspections. CDHS and CMS have indicated that if we fail to correct a total of six of the deficiencies, relating primarily to personnel licensing and the enforcement of regulatory requirements, we could face monetary and other penalties, up to and including revocation of our CLIA-88 license. We submitted a response and corrective action plan to CDHS in December 2001 in response to the CDHS statement of deficiencies. A more detailed response and corrective action plan was submitted to CMS in February 2002 in response to the CMS statement of deficiencies. By letter dated February 28, 2002, CDHS determined that the December 2001 submission did not constitute a credible allegation of compliance. CDHS and CMS are currently reviewing the February 2002 submission.

Compliance

We have reviewed the pertinent regulations of CLIA-88 and related rulings and policy guidelines and believe that our business practices adhere to the stated requirements. We will continue to monitor legislation and implement required guidelines or regulations. However, there can be no guarantee that we will pass all future inspections or otherwise be found to be in full compliance with these and other regulations.

The Department of Health and Human Services' (HHS) Office of the Inspector General has suggested that laboratories adopt a written compliance plan to promote standards of ethics and business practice that will help to prevent fraudulent conduct. We have adopted such a compliance plan and have appointed a Compliance Director to assist us with our regulatory compliance.

"Corporate Practice" of Medicine

California law, as well as the laws of many other states, prohibit physicians from sharing professional fees with non-physicians such as laboratories, and prohibit non-physicians from practicing medicine, including pathology, and from employing pathologists or other physicians. California law provides that the practice of medicine without a license is a misdemeanor, and a violation of the laws governing the practice of medicine could be a basis for assessment of fines and penalties, imposition of a cease and desist order, and the suspension or revocation of a California laboratory license. State and federal law also prohibit us from being compensated for referrals we make to our pathologists. We have previously employed pathologists, and are in the process of restructuring our relationships with pathologists in a manner that we believe does not violate any prohibition against the "corporate practice" of medicine. We do not believe that any violations which we may have committed in the past

are likely to result in sanctions that would have a material adverse effect on our business, financial condition, results of operations, or cash flows.

Increased Regulation of Genetic Testing

The federal Food and Drug Administration (FDA) regulates the manufacture of medical devices, including laboratory testing equipment, diagnostic kits and certain reagents. While the FDA believes that it has authority to regulate tests developed by laboratories for their own use, the FDA, to date, has allowed the development of such tests to proceed under the regulations under CLIA-88 governing a laboratory's development of its own assays. The FDA is testing methods for laboratories to register their in-house assays. The FDA has also subjected the commercialization of certain immunohistochemical stains, tumor markers and analyte specific reagents to limited regulation, and requires us to make certain disclosures in connection with their use. The federal Centers for Disease Control and Prevention (CDC) is revising the regulations under CLIA-88 to specifically recognize and regulate a genetic testing specialty. In addition, the Department of Health and Human Services' (HHS) Secretary's Advisory Committee on Genetic Testing (SACGT) advises the HHS as to various issues raised by the development and use of genetic testing. SACGT has published recommendations that include FDA review of individual tests, and augmentation of revised CLIA-88 standards to be written by the CDC. Our existing and future assays may be subject to federal regulatory approval similar to the pre-marketing approval process that the FDA applies to drugs and medical devices, or may be subject to other increased regulatory standards, which could have a negative effect on our business. At the state level, the New York State Department of Health now requires detailed review of our scientific validations and technical procedures for each assay before approval for NY residents; the level of scrutiny delays test availability.

Other Regulations

Pursuant to the Occupational Safety and Health Act (OSHA), laboratories must provide a safe workplace to their employees. In response to this requirement, OSHA has issued rules and regulations to protect workers from blood-borne pathogens and other hazards that are commonly found in laboratories. We are also subject to licensing and regulation under federal, state and local laws relating to the handling and disposal of medical specimens, hazardous waste and radioactive materials. We are also subject to regulations of the Department of Transportation, the Public Health Service's Centers for Disease Control & Prevention and the Postal Service which apply to the surface and air transportation of laboratory specimens. Although we believe that we are currently in compliance in all material respects with the above laws, failure to comply could subject us to denial of the right to conduct business, fines, criminal penalties and other enforcement actions.

Changes in Laboratory Reimbursement

Health Care Reform

A number of proposals aimed at increasing healthcare insurance coverage or reducing healthcare costs have been considered in recent years which, if enacted, would have affected major reforms of the healthcare system. Such proposals include: increased enrollment of Medicare beneficiaries in managed care systems, increased availability of health insurance to individuals and to small businesses, requirements that all businesses offer health insurance coverage to their employees, the provision of tax credits for purchase of health insurance, the formation of regional "health alliances" to act as healthcare purchasing agents and the creation of a government health insurance plan that would cover all citizens. We cannot predict whether any of these or other proposals will be adopted at the state or federal levels, or what effect, if any, such proposals would have on our business.

Reductions to Medicare or Medicaid Fee Schedules

For testing performed other than for hospitals, nursing facilities and other laboratories, laboratories are required to bill Medicare and Medicaid directly, and generally must accept reimbursement from these programs as payment in full for services performed for Medicare and Medicaid patients. Such direct billings by us to Medicare accounted for approximately 4.0% of our net revenue in 2000 and approximately 3.4% of our net revenue in 2001. Medicaid net revenue was 1.5% of our net revenue in 2000 and approximately 1.4% of our net revenue in 2001. However, a substantial portion of the testing for which we bill our hospital and independent laboratory customers is for Medicare and Medicaid patients, and we do not know the percentages of our net revenue that are indirectly derived from these programs. Any pricing pressure exerted by these programs on our customers may cause them to reduce their payments to us.

Congress has established maximum fee schedules for clinical laboratory testing performed for Medicare beneficiaries, excluding hospital and nursing facility inpatients. Payment for inpatient laboratory services is included in the prospective payment rates paid to the patient's facility. State Medicaid programs are prohibited from paying more for testing than the Medicare fee schedule amounts and, in most instances, they pay significantly less. When initially established, the Medicare fee schedules were set at 60% of prevailing local charges. Maximum reimbursement rates for clinical laboratory testing have subsequently been substantially reduced, and it should be expected that such fee schedules will be further reduced in the future. For example, a ceiling on Medicare and Medicaid payments to laboratories commonly referred to as the "national cap" amount has been reduced numerous times in recent years. Most recently, Congress reduced the national cap to 74% of the national median of local fee schedules and eliminated consumer price index increases to the national cap and local fee schedules through the year 2002. Medicare reimbursement has also been reduced from time to time by an effective rate of between 1% and 2% pursuant to Gramm-Rudman-Hollings sequestration. In addition, from time to time, proposals have been made that beneficiary cost sharing again be applied to laboratory testing paid for by Medicare. For example, such a recommendation is contained in the HHS Office of Inspector General's 2001 "Red Book" of suggested Medicare program improvements. The costs of billing and collecting co-payment amounts and associated bad debt could reduce the revenue actually realized by laboratories.

Medicare Reimbursement for Technical Component of Hospital Pathology Services. In the past, independent laboratories have been permitted to bill for the technical component of certain pathology services which are performed for Medicare hospital patients. CMS has promulgated regulations to end such separate billing as of January 1, 2001. Congress has enacted legislation delaying implementation of the CMS rules until January 1, 2003 for hospitals who had qualifying outsourcing contracts for pathology services in place as of July 22, 1999. Any such services we perform for hospitals without qualifying arrangements or after the January 1, 2003 date will have to be billed to the patient's hospital. Hospitals will receive no additional reimbursement from Medicare for these pathology services provided to inpatients, and reimbursement for these services under the new outpatient prospective payment system generally may be lower than it was previously. Such changes therefore may result in a reduction in the payments we receive from hospitals for these services.

Elimination of Dual Charge Structure. Proposals have been made to restrict "dual charge" billing practices under which laboratories charge higher fees to Medicare and Medicaid than are charged to physicians, hospitals, laboratories and other purchasers who are in a position to negotiate favorable rates. Thus, it has been proposed that existing authority for HHS to exclude from Medicare and Medicaid program participation any providers that charge amounts to the Medicare program that are "substantially in excess" of their "usual charges" be used to respond to laboratory pricing practices. Similarly, CMS is permitted to adjust statutorily prescribed fees for some medical services, including clinical laboratory services, if the fees are grossly excessive and therefore not inherently reasonable. CMS has issued an interim final rule setting forth criteria to be used in determining whether the

otherwise statutorily prescribed fees should be reduced which includes consideration of whether such fees are grossly higher or lower than the payment made for the services by other purchasers in the same locality. Fees payable by Medicare for clinical laboratory services may be reduced as a result of the application of the above rules or by similar restrictions which may be applied in the future.

In addition, the California Medi-Cal program is required by California regulations to pay no more for testing than the amount which a laboratory charges pursuant to any fee schedule it applies generally to its physician or hospital customers. While the extent to which this rule applies to our discounts which are negotiated on a case-by-case basis is unclear, it is possible that a recoupment action could be brought against us based upon discounts which we give to certain customers.

Contracts for Laboratory Services. Proposals have been made to require competitive bidding procurement of Medicare laboratory testing services. CMS is required to complete five Medicare bidding demonstrations involving various types of medical services by 2002, and CMS is expected to include a clinical laboratory demonstration project in a metropolitan statistical area. Similarly, California legislation requires the implementation of a program of negotiated laboratory service contracting for the Medi-Cal program. In addition, a large portion of the Medi-Cal program has been converted into a managed care system, resulting in negotiated laboratory service contracts between laboratories and other providers of healthcare services. Increased enrollment of Medicare or Medicaid beneficiaries in HMOs or negotiated contracting arrangements may also result in a larger portion of our business being subject to negotiated contracts with payors.

To obtain competitively bid contracts to perform services, it might be necessary for us to agree to substantial reductions in our payments from the Medicare and Medi-Cal programs. Such contracts may be exclusive and laboratories which do not hold such contracts may be denied access to the Medicare/Medi-Cal testing market and could have difficulty obtaining private patient testing from physicians participating in the contracting or managed care program.

“Bundling” of Medicare Services. Proposals have been made to reimburse clinical laboratory testing services as part of a larger “bundle” of healthcare services. Under one proposal, physicians would be reimbursed an additional amount for each office visit they had with a Medicare beneficiary and would be responsible for paying for any required laboratory services out of this sum. This or other “bundling” proposals, if enacted, could have an adverse effect on our operations.

Nongovernmental Efforts. Managed care arrangements may become increasingly prevalent in the clinical laboratory services market. For example, HMOs, insurance companies and self-insured employers may provide laboratory services directly or contract with laboratories at favorable fee-for-service or capitated rates and require their enrollees to obtain service only from such contracted laboratories. To the extent that we or our customers are unable to obtain contracts to provide such testing services or must discount prices to obtain such contracts, our revenues and profit margins could be adversely affected.

Requirements of Diagnosis Codes

Certain tests are only reimbursable by Medicare when the laboratory submits an appropriate diagnosis code which it has obtained from the ordering physician. California’s Medicaid program, known as Medi-Cal, has adopted, and is in the process of implementing, a policy requiring that a diagnosis code be submitted in connection with all bills for laboratory tests which are submitted to the Medi-Cal program where Medicare would require a diagnosis code if it were being billed for the tests. To the extent that the requirements for such diagnosis codes are expanded to additional tests or are adopted by additional Medicaid programs or by private insurance programs, or we are unable to obtain required codes from physicians, our reimbursement could be adversely affected.

Privacy of Medical Information

The confidentiality of patient medical information is subject to substantial regulation by state and the federal governments. Specific state and federal laws and regulations govern both the disclosure and use of confidential patient medical information, as well as access of patients to their own medical records. Similarly, many other federal laws also may protect such information, including the Electronic Communications Privacy Act of 1986 and federal laws relating to confidentiality of mental health records and substance abuse treatment.

Congress passed the Health Insurance Portability and Accountability Act, known as HIPAA, in 1996. Among other things, HIPAA calls for the establishment of national standards to facilitate the electronic exchange of health information and to maintain the security of both the health information and the system that enables the exchange of this information. HHS has promulgated several sets of proposed regulations pursuant to its authority under HIPAA. To date, the HIPAA regulations that have been finalized pertain to the security of individually identifiable health information that is electronically maintained or transmitted and the privacy of individually identifiable health information that is transmitted, received and maintained in any form or medium. Pursuant to these final regulations, all medical records and other patient identifiable health information must be maintained in confidence, must not be used for non-health purposes and must be disclosed to the minimum extent required. In addition, patients must be given a clear notice of their rights and access to their records by laboratories (other than to the extent that access to their records is restricted by CLIA and by state law) and a patient's consent or authorization generally must be obtained before information is released. To ensure that these requirements are satisfied, covered entities must adopt appropriate policies and practices, designate a privacy officer, train employees and establish a grievance procedure. The privacy regulations recognize, however, that laboratories have little direct contact with patients, and therefore they allow healthcare providers with an indirect treatment relationship to the patient to use protected health information for purposes of treatment and health care operations without a separate consent. Nonetheless, laboratories will still have to directly address HIPAA regulations in other circumstances.

In most circumstances, entities covered by HIPAA must be in compliance with the final HIPAA regulations within 24 months of the date the regulations become final (April 14, 2003, for the electronic privacy rules and October 16, 2002 for the electronic transaction rules). The Bush Administration has recently announced that it does not intend to further delay the implementation date of these regulations. If we are found to have violated any state or federal statute or regulation with regard to the confidentiality, dissemination or use of patient medical information, we could be liable for damages, or for civil or criminal fines or penalties. Because laboratory orders and reports fall within the scope of HIPAA, the costs of HIPAA compliance will impact us and others in the clinical laboratory industry. Compliance with the HIPAA rules could require us to spend substantial sums, which could negatively impact our profitability. At this time, we cannot assess the total financial or other impact of the HIPAA regulations upon us.

Recent Developments

On February 13, 2002, Beckman Coulter, Inc. and Specialty announced a cross-licensing agreement to collaborate on the development of novel multi-analyte assays based on Beckman Coulter's new Progressive MicroArray platform. Multi-analyte assays combine multiple testing analyses in a single testing process.

On February 26, 2002, Zyomyx, Inc. and Specialty announced an agreement to collaborate on the application of the Zyomyx Protein Profiling Biochip™ technology for clinical diagnostics. As part of the collaboration, the two companies will pursue the identification of new disease marker patterns by re-analyzing archived clinical specimen using the protein chip technology. The two companies have an

agreed structure whereby they share in the revenues generated by any potential assay or diagnostic kit resulting from the collaboration.

Employees

As of December 31, 2001, we employed 844 individuals. Thirty-eight are engaged in research and development, 197 in administration and clerical functions, 87 in sales and marketing, 50 in information technology and 472 in our clinical laboratory and related operations. None of our employees are represented by labor unions, and we believe our employee relations are good.

RISK FACTORS

This Annual Report contains forward-looking statements based on the current expectations, assumptions, estimates and projections about Specialty Laboratories, Inc. and the esoteric clinical laboratory industry. These forward-looking statements involve risks and uncertainties. Our actual results could differ materially from those discussed in these forward-looking statements as a result of certain factors, as more fully described in this section and elsewhere in this Annual Report. Specialty Laboratories, Inc. does not undertake to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

If advances in technology allow others to perform assays similar to ours, the demand for our assays may decrease.

The esoteric clinical laboratory industry is characterized by advancing technology which may enable other clinical laboratories, hospitals, physicians or other medical providers to perform assays with properties similar to ours in a more efficient or cost-effective manner than is currently possible. Such technological advances may be introduced by, not just our competitors, but by any third party. For instance, a diagnostic manufacturing company may release an instrument or technology that would make it cost-effective for our customers to perform esoteric assays internally, rather than through us. If these or other advances in technology result in a decreased demand for our assays, our assay volume and net revenue would decline.

The esoteric clinical laboratory industry is intensely competitive. If we are unable to successfully compete, we may lose market share.

The esoteric clinical laboratory industry is highly competitive. This industry is dominated by several national independent laboratories, but includes many smaller niche and regional independent laboratories as well. Our primary competitors include:

- large commercial enterprises, such as Quest Diagnostics, or Quest, and Laboratory Corporation of America, or LabCorp, that offer a wide test and product menu on a national scale;
- smaller niche laboratories like Impath or Athena Diagnostics that focus on a narrow segment of the esoteric market; and
- institutions such as Mayo Medical Laboratories, or Mayo, and Associated Regional University Pathologists, or ARUP, that are affiliated with large medical centers or universities.

Large commercial enterprises, including Quest and LabCorp, have substantially greater financial resources and may have larger research and development programs and more sales and marketing channels than we do, enabling them to potentially develop and market competing assays. These enterprises may also be able to achieve greater economies of scale or establish contracts with payor groups on more favorable terms. Smaller niche laboratories compete with us based on their reputation for offering a narrow test menu. Academic and regional institutions generally lack the advantages of the larger commercial laboratories but still compete with us on a limited basis.

Any of our competitors may successfully develop and market assays that are either superior to, or are introduced prior to, our assays. If we do not compete effectively with other independent clinical laboratories, we may be unable to maintain or grow our market share.

Intense competition and consolidation in our industry could materially adversely affect our business, financial condition, results of operations and prospects.

The clinical laboratory industry is intensely competitive and highly fragmented. Our current competitors include large national laboratories that offer a wide test and product menu on a national scale as well as smaller niche and regional organizations. Some of our large competitors have expanded, and may continue to expand, their competitive product offerings through acquisitions. For example, Quest, the nation's leading provider of diagnostic testing and related services for the healthcare industry, is in the process of acquiring American Medical Laboratories Incorporated, a national provider of esoteric testing to hospitals and specialty physicians. Acquisitions among existing and future competitors, may emerge and they may rapidly gain greater market share. In addition, some of our customers refer assays to us that they cannot perform themselves. These customers may no longer need to refer assays to us if they develop assays similar to us through the acquisition of other esoteric laboratories. A loss of market share and customers from such acquisitions could materially adversely affect our business, financial condition, results of operations and prospects.

Our operations and facilities are subject to stringent laws and regulations and if we are unable to comply, our business may be significantly harmed.

As a provider of healthcare-related services, we are subject to extensive and frequently changing federal, state and local laws and regulations governing licensure, billing, financial relationships, referrals, conduct of operations, purchases of existing businesses, cost-containment, direct employment of licensed professionals by business corporations and other aspects of our business relationships.

If we do not comply with existing or additional laws or regulations, or if we incur penalties, it could increase our expenses, prevent us from increasing net revenue, or hinder our ability to conduct our business. In addition, changes in existing laws or regulations, or new laws or regulations, may delay or prevent us from marketing our products or cause us to reduce our pricing.

Fraud and Abuse

Of particular importance to our operations are federal and state laws prohibiting fraudulent billing and providing for the recoupment of non-fraudulent overpayments, as a large number of laboratories have been forced by the federal and state governments, as well as by private payors, to enter into substantial settlements under these laws. Government investigations of clinical laboratories have been ongoing for a number of years and are expected to continue in the future. Written "corporate compliance" programs to actively monitor compliance with fraud laws and other regulatory requirements are recommended by the Department of Health and Human Services' Office of the Inspector General and we have a program following the guidelines in place.

Federal and State Clinical Laboratory Licensing

The operations of our clinical laboratory are subject to a stringent level of regulation under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). For certification under CLIA-88, laboratories such as ours must meet various requirements, including requirements relating to quality assurance, quality control and personnel standards. Since we perform patient testing from all states, our laboratory is also subject to strict regulation by California, New York and various other states. We are accredited by the College of American Pathologists, a private accrediting agency, and therefore are subject to their requirements and evaluation. Our failure to comply with CLIA-88, state or other

applicable requirements could result in various penalties, including restrictions on tests which the laboratory may perform, substantial civil monetary penalties, imposition of specific corrective action plans, suspension of Medicare payments and/or loss of licensure, certification or accreditation. Such penalties could result in our being unable to continue performing laboratory testing. Compliance with such standards is verified by periodic inspections and requires participation in proficiency testing programs.

In June and October, 2001, we underwent unannounced inspections by the California Department of Health Services, or CDHS, representing both the State of California and acting as agent of the federal Center for Medicare and Medicaid Services, or CMS, under CLIA-88. As a result, the laboratory was cited by CDHS with 20 deficiencies under California law and CLIA-88. A separate statement indicating 12 overlapping deficiencies under CLIA-88 was issued by CMS in February 2002 based upon the same inspections. CDHS and CMS have indicated that if we fail to correct a total of six of the deficiencies, relating primarily to personnel licensing and the enforcement of regulatory requirements, we could face monetary and other penalties, up to and including revocation of our CLIA-88 license. We submitted a response and corrective action plan to CDHS in December 2001 in response to the CDHS statement of deficiencies. A more detailed response and corrective action plan was submitted to CMS in February 2002 in response to the CMS statement of deficiencies. By letter dated February 28, 2002, CDHS determined that the December 2001 submission did not constitute a credible allegation of compliance. CDHS and CMS are currently reviewing the February 2002 submission.

Although we believe that we will be able to correct any deficiencies, no assurances can be given that our facilities will pass all future inspections conducted to ensure compliance with federal or any other applicable licensure or certification laws. Any inability to comply with federal, state or other applicable regulations could result in substantial monetary penalties, suspension of Medicare payments and/or loss of licensure, certification or accreditation. In addition, substantial expenditures are required on an ongoing basis to ensure that we comply with existing regulations and to bring us into compliance with newly instituted regulations.

Food & Drug Administration

Neither the FDA nor any other governmental agency currently fully regulates the new assays we internally develop. Although the FDA previously asserted that its jurisdiction extends to tests generated in a clinical laboratory, it has allowed these tests to be run and the results commercialized without FDA premarket approval. However, we cannot predict the extent of future FDA regulation and there can be no assurance that the FDA will not consider testing conducted at a clinical laboratory to require premarketing clearance. Hence, we might be subject in the future to greater regulation, or different regulations, that could have a material effect on our finances and operations.

Anti-Kickback Regulations

Existing federal laws governing Medicare and Medicaid and other similar state laws impose a variety of broadly described restrictions on financial relationships among healthcare providers, including clinical laboratories. These laws include federal anti-kickback laws which prohibit clinical laboratories from, among other things, making payments or furnishing other benefits intended to induce the referral of patients for tests billed to Medicare, Medicaid or certain other federally funded programs. In addition, they also include self-referral prohibitions which prevent us from accepting referrals from physicians who have non-exempt ownership or compensation relationships with us as well as anti-markup and direct billing rules that may apply to our relationships with our customers. Sanctions for violations of these laws may include exclusion from participation in Medicare, Medicaid and other federal healthcare programs, and criminal and civil fines and penalties.

Fee-Splitting

The laws of many states prohibit physicians from sharing professional fees with non-physicians and prohibit non-physician entities, such as us, from practicing medicine and from employing physicians to practice medicine. If we do not comply with existing or additional regulations, or if we incur penalties, it could increase our expenses, prevent us from increasing net revenue, or hinder our ability to conduct our business. In addition, changes in existing regulations or new regulations may delay or prevent us from marketing our products or cause us to reduce our pricing.

If we do not comply with laws and regulations governing the confidentiality of medical information, it will adversely affect our ability to do business.

The confidentiality of patient medical information is subject to substantial regulation by the state and federal governments. State and federal laws and regulations govern both the disclosure and the use of confidential patient medical information. Most states have laws that govern the use and disclosure of patient medical information and the right to privacy. Similarly, many federal laws also may apply to protect such information, including the Electronic Communications Privacy Act of 1986 and federal laws relating to confidentiality of mental health records and substance abuse treatment.

Legislation governing the dissemination and use of medical information is continually being proposed at both the state and federal levels. For example, the Health Insurance Portability and Accountability Act of 1996, known as HIPPA, requires the Secretary of Health and Human Services (HHS) to develop regulations to protect the security and privacy of individually identifiable health information that is electronically transmitted or received. In November 1999, the Secretary of HHS published proposed regulations under the HIPPA that would protect the privacy of individually identifiable health information that is transmitted or received electronically. Prior to that, the Secretary of HHS published proposed regulations relating to security of individually identifiable health information. When and if the security regulation becomes final, and if the privacy regulation is not modified by HHS or invalidated by Congress under the Congressional Review Act, then they will require that holders or users of electronically transmitted patient health information implement measures to maintain the security and privacy of such information. Ultimately, this and other legislation may even affect the dissemination of medical information that is not individually identifiable. Physicians and other persons providing patient information to us are also required to comply with these laws and regulations. If a patient's privacy is violated, or if we are found to have violated any state or federal statute or regulation with regard to the confidentiality, dissemination or use of patient medical information, we could be liable for damages, or for civil or criminal fines or penalties.

The commercialization of our Internet products including Outreach Express™, DataPassportMD™, and DataPassport Clinical Trials™ is strictly governed by state and federal laws and regulations, including the new and proposed regulations under HIPPA. We have implemented encryption technology to protect patient medical information, however, use of encryption technology does not guarantee the privacy and security of confidential information. We believe that we are in material compliance with all currently applicable state and federal laws and regulations governing the confidentiality, dissemination and use of medical record information. However, differing interpretations of existing laws and regulations, or the adoption of new laws and regulations, could reduce or eliminate our ability to obtain or use patient information which, in turn, could limit our ability to use our information technology products for electronically transmitting patient data.

The premium prices that we initially charge for new assays may drop if our competitors are able to develop and market competing assays more quickly than they currently do.

Typically, we market new esoteric assays at premium prices for several years before similar assays are developed as either standardized prepared kits for broad application or as internally developed

assays by competing laboratories. The opportunity to sell our products at premium prices may be reduced or eliminated if our competitors are able to develop and market competing assays more quickly than they currently do. If we are unable to develop newer assays which meet market demand, our net revenue and profit margins may decrease.

Some of our customers are also our primary competitors. If they reduce or discontinue purchasing our assays for competitive reasons, it will reduce our net revenue.

Some of our customers, such as Quest, LabCorp, Mayo and ARUP, also compete with us by providing esoteric testing services. They often refer assays to us that they either cannot or elect not to perform themselves. For the year ended December 31, 2001, sales to our competitors were approximately \$10 million or approximately 6% of our net revenue. These parties may decide not to refer assays to us because they wish to develop and market assays similar to ours. For example, in July 1997, SmithKline Beecham Clinical Laboratories, or SmithKline Labs, began to significantly limit the number of assays it referred to us. We believe that SmithKline Labs terminated its relationship with us because it decided to offer assays similar to ours. In 1996, SmithKline Labs comprised 21.7% of our net revenue, whereas in 2001, after being acquired by Quest, SmithKline Labs (excluding Quest accounts prior to the acquisition) only comprised approximately 2% of our net revenue. If other independent laboratories decide to reduce or discontinue purchases of our assays for competitive reasons, it will reduce our net revenue.

If we are unable to develop and successfully market new assays or improve existing assays in a timely manner, our profit margins may decline.

In order to maintain our margins and benefit from the premium prices that we typically charge for our newly introduced esoteric assays, we must continually develop new assays and improve our existing assays through licensing arrangements with third parties and through the efforts of our R&D department. There is no assurance, however, that we will be able to maintain our current pace of developing and improving assays in the future. Even if we develop such assays in a timely manner, our customers may not utilize these new assays. If we fail to develop new technologies, release new or improved assays on a timely basis, or if such assays do not obtain market acceptance, our profit margins may decline.

If we fail to acquire licenses for new or improved assay technology platforms, we may not be able to accelerate assay improvement and development, which could harm our ability to increase our net revenue.

Our ability to accelerate new assay development and improve existing performance will depend, in part, on our ability to license new or improved assay technology platforms on favorable terms. We may not be able to negotiate acceptable licensing arrangements and we cannot be certain that such arrangements will yield commercially successful assays. Further, even if we enter into such arrangements with these third parties, their devotion of resources to these efforts may not be within our control or influence. If we are unable to license these technologies at competitive rates, our research and development costs may increase. In addition, if we are unable to develop new or improved assays through such research and development efforts, our assays may be outdated when compared with our competition's assays, and our net revenue may decrease.

A significant portion of our net revenue depends on a single customer, Unilab Corporation. If our relationship with Unilab is terminated or not renewed, our business may suffer.

For the years ended December 31, 2001 and 2000, services to Unilab Corporation accounts comprised less than 8.0% and 9.6% of our net revenue, respectively. Although we have entered into an agreement with Unilab in which it has agreed to refer to us, until the agreement expires in

October 2002, at least 90% of the esoteric laboratory services it outsources each year or, in the event of a change of control of Unilab or the purchase by Unilab of a licensed clinical laboratory with a test menu materially broader than that of Unilab, at least \$800,000 of esoteric laboratory services per month, there is no assurance that it will uphold this obligation. In addition, if Unilab does not renew this agreement in October 2002, it will then no longer be under any obligation to provide us with minimum assay referrals. If, for any reason, Unilab's purchase of our services were to be materially reduced or if Unilab failed to renew its contract with us in October 2002, it may decrease our net revenue.

If group purchasing organizations do not renew and maintain our contracts, we may lose an important mechanism by which to further penetrate the hospital customer base.

Many of our existing and potential hospital customers are part of group purchasing organizations, which typically pool independent hospitals together to negotiate for pricing and services, including prices for laboratory tests. These group purchasing organizations provide incentives to their participating hospitals to utilize clinical laboratories which have contracts with the group purchasing organizations.

Our participation in group purchasing organizations constitutes one aspect of our overall strategy to attract new hospital customers. We have contracts with five group purchasing organizations: AmeriNet, Health Services Corporation of America, Managed Healthcare Associates, Novation (formerly known as VHA) and Shared Services Healthcare. We are typically granted non-exclusive provider status under these contracts. Our contracts with our group purchasing organizations will expire at times from 2003 to 2004.

For the year ended December 31, 2001, sales of our services to hospitals which utilized the pricing structures under the Novation and AmeriNet group purchasing organization contracts comprised approximately \$40 million or approximately 24% of our net revenues, and approximately \$8 million or approximately 5% of our net revenues, respectively. Sales to hospitals within the other three group purchasing organizations comprised less than 3% of our net revenues for the same period. These group purchasing organizations offer a substantial growth opportunity to gain additional revenue from existing hospital customers.

We cannot be certain that if our agreement with Novation, AmeriNet or any other group purchasing organization is terminated or not renewed, we will be able to retain any of the accounts of the participating hospitals. If any hospital customer affiliated with a group purchasing organization no longer uses our services, it will reduce our net revenue. In addition, if we are unable to attract new hospital customers because any group purchasing organization contract is terminated, it may adversely affect our ability to grow our business.

Failure in our information technology systems could significantly increase turn-around time, reduce our production capacity, and otherwise disrupt our operations, which may reduce our customer base and result in lost net revenue.

Our success depends, in part, on the continued and uninterrupted performance of our information technology systems, including our DataPassport® suite of products. Sustained or repeated system failures that interrupt our ability to process assay orders, deliver assay results or perform assays in a timely manner would reduce significantly the attractiveness of our products to our customers. Our business, financial condition, results of operations, or cash flows could be materially and adversely affected by any damage or failure that interrupts or delays our operations.

Our computer systems are vulnerable to damage from a variety of sources, including telecommunications failures, malicious human acts and natural disasters. Moreover, despite network security measures, some of our servers are potentially vulnerable to physical or electronic break-ins,

computer viruses and similar disruptive problems, in part because they are located at a third party web hosting company, Exodus Communications, in El Segundo, California, and we cannot control the maintenance and operation of the Exodus data centers. Despite the precautions we have taken, unanticipated problems affecting our systems could cause interruptions in our information technology systems.

We have several different insurance policies designed to cover losses arising from such interruptions. However, these insurance policies may not adequately compensate us for any losses that may occur due to any failures in our systems.

Change of our web hosting company from Exodus Communications to another provider of services could result in a disruption of our operations, and our business, results of operations and financial condition could be materially and adversely affected by any damage or failure that interrupts or delays our operations.

Some of our network servers are located at a third party web hosting company, Exodus Communications, in El Segundo, California. Exodus Communications filed for Chapter 11 bankruptcy protection in September of 2001, and certain assets of Exodus have apparently been acquired by Cable & Wireless plc. While the server hosting operations have so far continued uninterrupted, and not yet affected any of our operations, we are in the process of changing our network server hosting service to another provider. We expect to complete the move to another provider sometime in the first half of 2002.

We cannot guarantee that our operations will be unaffected by Exodus' bankruptcy, or the asset purchase by Cable & Wireless. Furthermore, the actions of transferring our network service hosting to another provider could result in interruption and or delays in our operations. While we are building a parallel system at the new service provider, and are taking other precautions to prevent any such interruption or delay in our operations, we cannot guarantee that the act of moving to a different service provider will not result in such interruptions or delays in our operations. Moreover, despite changing web-hosting providers, some of our servers will remain potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems, in part because they will remain at a third party web hosting company, and we cannot control the maintenance and operation of the data centers. Despite the precautions we have taken, unanticipated problems affecting our systems could cause interruptions in our information technology systems. Our business, financial condition, results of operations, or cash flows could be materially and adversely affected by any problem that interrupts or delays our operations.

While we have insurance policies that may cover losses arising from such interruptions, these insurance policies may not adequately compensate us for any losses that may occur due to any failures in our systems as a result of moving to a new provider, or any losses that may occur due to any failures in our systems.

If we lose our competitive position in providing valuable information technology solutions as an ancillary service to our customers, we may not be able to maintain or grow our market share.

Over the past five years, we have made a substantial investment in our information technology solutions, such as DataPassport® and DataPassportMD™, to facilitate electronic assay ordering and results reporting as a value added service for our customers. We believe that these solutions are one factor considered by our customers when selecting a reference laboratory. In the future, our competitors may offer similar or better information technology solutions to our existing and potential customer base. If this occurs, we will lose this competitive advantage, and as a result, may be unable to maintain or increase our market share.

We rely on a few assays for a significant portion of our net revenue. If demand for these assays were to weaken for any reason, our net revenue would decrease.

A significant portion of our net revenue is derived from 30 assays. Net revenue from these 30 assays comprised approximately 45% of our total net revenue for the year ended December 31, 2001 and approximately 49% for the year ended December 31, 2000. In addition, only one assay, HIV Quantitation, accounted for approximately 10% of our net revenue in one of the past three years. In 2001, no assay accounted for 10% or more of our net revenue. If competing assays are introduced by competitors or demand for these assays otherwise decreases, our net revenue could decrease.

Clinicians or patients using our products or services may sue us and our insurance may not sufficiently cover all claims brought against us, which will increase our expenses.

The development, marketing, sale and performance of healthcare services exposes us to the risk of litigation, including medical malpractice. Damages assessed in connection with, and the costs of defending, any legal action could be substantial. We currently maintain insurance with coverage up to \$20 million, either singly or in the aggregate, which we believe to be adequate to cover our exposure in our current professional liability claims and employee-related matters which were incurred in the ordinary course of business. Although we believe that these claims may not have a material effect on us, because we expect them to be covered by this insurance, we may be faced with litigation claims which exceed our insurance coverage or are not covered under our insurance policy. In addition, litigation could have a material adverse effect on our business if it impacts our existing and potential customer relationships, creates adverse public relations, diverts management resources from the operation of the business or hampers our ability to perform assays or otherwise conduct our business.

If protection of the intellectual property underlying our technology and trade secrets is inadequate, then third parties may be able to use our technology or similar technologies, thus reducing our ability to compete.

We currently rely on certain technologies for which we believe patents are not economically feasible and therefore may be developed independently or copied by our competitors. Furthermore, we rely on certain proprietary trade secrets and know-how, which we have not patented. Although we have taken steps to protect our unpatented trade secrets and know-how, principally through the use of confidentiality agreements with our employees, there can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently developed or discovered by competitors. If our trade secrets become known or are independently developed or discovered by competitors, it could have a material adverse effect on our ability to compete.

Our assays may infringe on the intellectual property rights of others, which may cause us to engage in costly litigation which may cause us to pay substantial damages and prohibit us from selling our assays.

Other companies or institutions engaged in assay development, including our competitors, may obtain patents or other proprietary rights that would prevent, limit or interfere with our ability to develop, perform or sell our assays. As a result, we may be found to be, or accused of, infringing on the proprietary rights of others. For example, in response to a patent infringement allegation from Athena Diagnostics in 1997, we ceased performing an assay used to diagnose late onset Alzheimer's disease. We have received letters from Chiron Corporation in February 1998, and from the National Institute of Health in April 2000 and June 2001, claiming that some of our assays may violate their patents. The assays which may be affected by these claims comprised approximately \$18 million of our net revenue for the year ended December 31, 2001. While management believes that none of these claims will have a material adverse effect on our business, there can be no assurance that there will be

no adverse consequences to us. As a result of these claims and any other infringement related claims, we could incur substantial costs in defending any litigation, and intellectual property litigation could force us to do one or more of the following:

- cease developing, performing or selling products or services that incorporate the challenged intellectual property;
- obtain and pay for licenses from the holder of the infringed intellectual property right; or
- redesign or reengineer our assays.

Any efforts to reengineer our assays or any inability to sell our assays could substantially increase our costs, force us to interrupt product sales, delay new assay releases and ultimately, reduce our revenues.

We may acquire other businesses, products or technologies in order to remain competitive in our market and our business could be adversely affected as a result of any of these future acquisitions.

We have made in the past and we may continue to make acquisitions of complementary businesses, products or technologies. In this regard, we acquired BBI Clinical Laboratories, Inc. in February 2001. If we identify any additional appropriate acquisition candidates, we may not be successful in negotiating acceptable terms of the acquisition, financing the acquisition, or integrating the acquired business, products or technologies into our existing business and operations. Further, completing an acquisition and integrating an acquired business will significantly divert management time and resources. The diversion of management attention and any difficulties encountered in the transition and integration process could harm our business. If we consummate any significant acquisitions using stock or other securities as consideration, your equity in us could be significantly diluted. If we make any significant acquisitions using cash consideration, we may be required to use a substantial portion of our available cash. Acquisition financing may not be available on favorable terms, if at all. In addition, we may be required to amortize significant amounts of other intangible assets in connection with future acquisitions, which would harm our operating results.

We may encounter problems or delays in operating or implementing our automated processing systems, which could disrupt our operations, require us to develop alternatives and increase our costs.

In order to meet growth in demand for our esoteric assays, we will have to process many more patient samples than we are currently processing. We have implemented a high-speed specimen sorting system known as the Total Accessioning Re-Organization System, or TARO™. In addition, we plan to develop and implement other automated systems to enhance our testing procedures, including the implementation of a specimen splitting system, designated as HANA™. We will need to develop sophisticated software to support these other automated procedures, analyze the data generated by these tests and report the results. Further, as we attempt to increase the number of patient samples we process, throughput or quality-control problems may arise.

If we are unable to consistently process patient samples on a timely basis because of delays or failures in our implementation of these automated systems, or if we encounter problems with our established automated processes, we will be required to develop alternate means to process our business which may increase our costs.

Our net revenue will be diminished if payors do not authorize reimbursement for our services.

There has been and will continue to be significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement government control of healthcare costs. In addition, increasing emphasis on managed care in the U.S. may continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the reimbursement status of new assays. Third party payors, including state payors and Medicare, are challenging the prices charged for medical products and services. Government and other third party payors increasingly are limiting both coverage and the level of reimbursement for our services. Third party insurance coverage may not be available to patients for any of our existing assays or assays we discover and develop. Third party payors accounted for approximately 7.3% of our net revenue in 2000 and approximately 6.9% of our net revenue in 2001. However, a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third party payors and we do not know the percentage of our net revenue that is indirectly derived from these payors. Any pricing pressure exerted by these third party payors on our customers may, in turn, be exerted by our customers on us. If government and other third party payors do not provide adequate coverage and reimbursement for our assays, our net revenue may decline.

If a catastrophe were to strike our clinical laboratory facility, we would be unable to process our customers' samples for a substantial amount of time and we would be unable to operate our business competitively.

Our clinical and processing facility may be affected by catastrophes such as earthquakes or sustained interruptions in electrical service. Earthquakes are of particular significance to us because all of our clinical laboratory facilities are located in Santa Monica, California, an earthquake-prone area. In the event our existing clinical laboratory facility or equipment is affected by man-made or natural disasters, we would be unable to process our customers' samples in a timely manner and unable to operate our business in a commercially competitive manner. To address these risks, we have in place formal recovery plans for all interruptions of service. This includes identification of alternate laboratory testing facilities and disaster recovery protocols. We also carry earthquake insurance with a coverage amount of up to \$10 million and we have outsourced part of our data storage and processing equipment to a facility designed to withstand most earthquakes. Despite these precautions, the self-insured retention amount for earthquake insurance is very high, and there is no assurance that we could recover quickly from a serious earthquake or other disaster.

We rely on a continuous power supply to conduct our operations, and California's current energy crisis could disrupt our operations and increase our expenses.

All of our laboratory operations are located in Santa Monica, California and we plan to move our operations to Valencia, California. California is still in an energy crisis that could disrupt our operations and increase our expenses. In the event power reserves for the state of California fall to critically low levels, California may implement rolling power blackouts throughout the state. The state of California has already experienced such occasional power blackouts. We currently have backup power generators for our laboratories in the event of a blackout. Our current insurance, however, does not provide coverage for any damages we may suffer as a result of any interruption in our power supply. If blackouts interrupt our third party power supply, we may be temporarily unable to continue operations. Any such interruption in our ability to continue operations would delay our processing of laboratory samples, disrupt communications with our customers and suppliers and delay product shipment. Power interruptions could also damage our reputation and could result in lost revenue. Any loss of power could have a material adverse effect on our business, operating results and financial condition. Furthermore, shortages in wholesale electricity supplies have caused power prices to increase. If

wholesale prices continue to increase, our operating expenses will likely increase which will have a negative effect on our operating results.

Disruption similar to the September 2001 terrorist attacks in the future on the U.S. may adversely impact our results of operations, future growth and stock price.

The operation of our laboratories have been and may continue to be harmed by the recent terrorist attacks on the U.S. For example, transportation systems and couriers that we rely upon to receive and process specimens have been, and may in the future, be disrupted. In addition, we may experience a rise in operating costs, such as costs for transportation, courier service, insurance and security. We may also experience delays in receiving payments from payors that have been affected by the attack, which, in turn, would harm our cash flow. The U.S. economy in general may be adversely affected by the terrorist attacks or by any related outbreak of hostilities. Any such economic downturn could adversely impact our results of operations, revenues and costs, impede our ability to continue to grow our business and may result in the volatility of the market price of our common stock and on the future price of our common stock.

Our quarterly operating results may fluctuate and this could cause our stock price to fluctuate or decline.

Our quarterly operating results have varied significantly in the past and may vary significantly in the future. If our quarterly net revenue and operating results fall below the expectations of securities analysts and investors, the market price of our common stock could fall substantially. Operating results vary depending on a number of factors, many of which are outside our control, including:

- demand for our assays and ancillary services;
- loss of a significant customer or group purchasing organization contract;
- new assay introductions by competitors;
- changes in our pricing policies or those of our competitors;
- the hiring and retention of key personnel;
- changes in healthcare laws and regulations; and
- costs related to acquisitions of technologies or businesses.

We plan to expand our sales and marketing, research and development and general and administrative efforts, which will lead to an increase in expenses. If our net revenue does not increase along with these expenses, our business, financial condition, results of operations, or cash flows could be materially harmed and operating results in a given quarter could be worse than expected.

For a more detailed description of our operating results, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Our stock price is likely to be volatile and could drop unexpectedly.

The price at which our common stock will trade is likely to be volatile. The stock market has from time to time experienced significant price and volume fluctuations that have affected the market prices of securities, particularly securities of clinical laboratory, biotechnology and other healthcare service companies. As a result, the market price of our common stock may materially decline, regardless of our operating performance. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. We may become involved in this type of litigation in the future. Litigation of this type is often expensive and diverts management's attention and resources.

We are controlled by a single existing shareholder, whose interests may differ from other shareholders' interests.

Our principal shareholder is Specialty Family Limited Partnership, whose sole general managing partner is our Chairman and Chief Executive Officer, James B. Peter, MD, PhD. Specialty Family Limited Partnership, together with Dr. Peter, currently beneficially own approximately 66% of the outstanding shares of our common stock. Accordingly, the Specialty Family Limited Partnership along with Dr. Peter will have significant influence in determining the outcome of any corporate transaction or other matter submitted to the shareholders for approval, including election of directors, mergers, consolidations and the sale of all or substantially all of our assets. Our principal shareholder will also have the power to prevent or cause a change in control. The interests of this shareholder may differ from other shareholders' interests. In addition, this concentration of ownership may delay, prevent, or deter a change in control and could deprive other shareholders of an opportunity to receive a premium for their common stock as part of a sale of our business.

Anti-takeover provisions in our charter documents could prevent or delay a change in control and, as a result, negatively impact our shareholders.

We have taken a number of actions that could have the effect of discouraging a takeover attempt. For example, provisions of our amended and restated articles of incorporation and amended and restated bylaws could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our shareholders. These provisions also could limit the price that certain investors might be willing to pay in the future for shares of our common stock.

These provisions include:

- limitations on who may call special meetings of shareholders;
- advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by shareholders at shareholder meetings; and
- the ability of our board of directors to issue preferred stock without shareholder approval.

ITEM 2. PROPERTIES

Our primary facility is located in Santa Monica, California and is comprised of four separate buildings totaling 85,357 square feet. Three of our building leases expire in 2003 and one building lease expires in 2004. Additionally, three of our leases have options for five additional years upon expiration of the current leases. Our production, research and administrative functions occupy these buildings. Annual rent for these four buildings is approximately \$1.6 million plus applicable property taxes, maintenance costs and utilities.

We also operate one stand-alone triage collection and processing center in Worcester, Massachusetts to serve Boston area customers. This facility contains 1,578 square feet and is leased at approximately \$34,700 per year on a month-to-month basis. We also occupy a smaller 210 square foot administrative facility at the same address.

In December 2001, we purchased a 13.8 acre site in Valencia, California. We plan to build a 195,000 square foot facility which will enable us to consolidate all of our laboratory and administrative functions in one location. We currently project construction to begin during second quarter 2002 with our move to the new facility planned for the second half of 2003. The facility's construction costs will be financed by an independent third party and, upon completion, the facility will be leased to the company.

ITEM 3. LEGAL PROCEEDINGS

In addition to the California state and federal investigations described in “Business—Government Regulation—Certification and Licenses”, “Risk Factors—Our operations and facilities are subject to stringent laws and regulations and if we are unable to comply, our business may be significantly harmed”, and “Management’s Discussion and Analysis of Financial Condition and Results of Operation—Subsequent Events”, we are involved in various legal proceedings arising in the ordinary course of business.

Specialty Laboratories Asia Pte. Ltd., a Singapore corporation, or SLA, is 60% owned by our wholly-owned subsidiary, Specialty Laboratories International Ltd., a British Virgin Islands corporation. SLA was headquartered in Singapore but, in early 1999, SLA ceased all operations and is currently insolvent. A former employee of SLA has obtained a judgment for \$350,000 against SLA and a default judgment of approximately \$1.95 million in a wrongful termination action against SLA filed by him in Singapore. The former employee has filed an action against SLA in California to attempt to collect on the Singapore judgment and has obtained a default judgment of approximately \$2.5 million against SLA in California. The former employee has served discovery upon Specialty and certain directors and officers. Our management believes that any claim against us or our directors and officers in connection with these judgments, if made, would be without merit, and we would vigorously defend any such action.

A former officer filed an action in federal district court against the Company and two of its officers alleging violations of federal and state securities laws and other causes of action in connection with the sale of the Company’s common stock by the former officer and the Company’s application of its insider trading policy. The Company’s motion to compel arbitration was granted. The matter has been submitted to binding arbitration before a former federal judge. Management believes the claims to be without merit and will vigorously defend this action.

From time to time, we receive letters alleging infringement of patent or other intellectual property rights. Our management believes that these letters generally are without merit and intend to contest them vigorously. For more information, please see “Risk Factors—Our assays may infringe on the intellectual property rights of others, which may cause us to engage in costly litigation which may cause us to pay substantial damages and prohibit us from selling our assays.”

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

PART II.

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON STOCK AND RELATED SHAREHOLDER MATTERS

Market Information

Our common stock has traded on the New York Stock Exchange under the symbol "SP" since December 7, 2000. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sales prices reported on the New York Stock Exchange for our common stock for the periods indicated.

	Price Range of Common Stock	
	High	Low
Year 2000:		
Fourth Quarter (December 7, 2000 through December 31, 2000)	\$35.50	\$21.38
Year 2001:		
First Quarter	\$33.375	\$16.75
Second Quarter	\$47.00	\$22.05
Third Quarter	\$38.76	\$20.50
Fourth Quarter	\$34.00	\$19.75
Year 2002:		
First Quarter (through February 28, 2002)	\$27.50	\$21.00

On February 28, 2002, the last reported sales price of our common stock was \$23.15.

Holders

As of February 28, 2002, there were 35 holders of record of our common stock.

Recent Sales of Unregistered Securities

None.

Dividend Policy

We have not declared or paid any cash dividends on our capital stock since 1992. We currently intend to retain future earnings, if any, to provide funds to finance the expansion of our business. In addition, in connection with a loan and security agreement, we are restricted from paying dividends in cash. As a result, we do not anticipate paying any cash dividends in the foreseeable future.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected financial data is derived from audited consolidated financial statements. The statement of operations data set forth below for the year December 31, 1997 is derived from our financial statements that have been audited and to which reclassifications have been made to conform to the presentation of costs and expenses, continuing operations, discontinued operations and net assets of discontinued foreign operations for the other periods presented. The consolidated statement of operations data for the years ended December 31, 1997 and 1998 and the consolidated balance sheet data at December 31, 1997, 1998 and 1999 were derived from our audited consolidated financial statements and are not included in this Annual Report. You should read the selected financial information set forth below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing elsewhere in this Annual Report.

	Years Ended December 31,				
	1997	1998	1999	2000	2001
	(amounts in thousands, except per share data)				
Statement of operations data:					
Net revenue	\$106,357	\$113,843	\$130,142	\$153,245	\$175,169
Costs and expenses:					
Costs of services	60,157	65,098	74,784	86,856	99,955
Selling, general and administrative (exclusive of stock-based compensation charges)	39,813	42,084	46,903	49,277	55,613
Stock-based compensation charges(1)	—	—	2,818	1,073	1,103
Write-down of unused facilities(2)	—	—	2,209	369	—
Total costs and expenses	99,970	107,182	126,714	137,575	156,671
Operating income	6,387	6,661	3,428	15,669	18,498
Interest (income) expense, net	883	1,159	1,639	941	(3,451)
Income from continuing operations before income taxes	5,504	5,502	1,789	14,729	21,949
Provision for income taxes	2,506	2,273	930	6,056	8,870
Income from continuing operations	2,998	3,229	859	8,673	13,079
Loss from discontinued operations(3)	(936)	(3,060)	(2,001)	—	—
Net income (loss)	\$ 2,062	\$ 169	\$ (1,142)	\$ 8,673	\$ 13,079
Income (loss) per share(4):					
Basic:					
Continuing operations	\$ 0.19	\$ 0.21	\$ 0.05	\$ 0.54	\$ 0.62
Discontinued operations	(0.06)	(0.20)	(0.12)	—	—
	\$ 0.13	\$ 0.01	\$ (0.07)	\$ 0.54	\$ 0.62
Diluted:					
Continuing operations	\$ 0.19	\$ 0.21	\$ 0.05	\$ 0.49	\$ 0.59
Discontinued operations	(0.06)	(0.20)	(0.12)	—	—
	\$ 0.13	\$ 0.01	\$ (0.07)	\$ 0.49	\$ 0.59
Other data:					
EBITDA(5)	\$ 9,942	\$ 10,844	\$ 8,837	\$ 21,621	\$ 25,486
EBITDA as a % of net revenue	9.3%	9.5%	6.8%	14.1%	14.5%
Adjusted EBITDA(5)	\$ 9,942	\$ 10,844	\$ 13,864	\$ 23,063	\$ 26,588
Adjusted EBITDA as a % of net revenue	9.3%	9.5%	10.7%	15.0%	15.2%
Cash flow provided by continuing operating activities	\$ 5,994	\$ 7,353	\$ 3,315	\$ 15,463	\$ 19,507
Cash flow used in investing activities	(15,128)	(5,131)	(3,696)	(5,965)	(82,531)
Cash flow provided by (used in) financing activities	11,047	2,942	(56)	65,388	2,603

	As of December 31,				
	1997	1998	1999	2000	2001
	(amounts in thousands)				
Balance sheet data:					
Working capital	\$2,899	\$2,035	\$3,616	\$88,789	\$58,736
Total assets	48,229	55,998	59,859	142,005	153,988
Long-term debt, including current portion	14,761	17,703	18,382	—	—
Total shareholders' equity	17,135	16,953	18,281	111,797	132,656

- (1) We recorded stock-based compensation charges of \$2.8 million for the year ended December 31, 1999 in connection with the sale of our common stock to management and the grant of stock options to management and directors in 1999. We recorded stock-based compensation charges of \$1.1 million for both the years ended December 31, 2000 and 2001 resulting from the amortization of deferred stock-based compensation and variable stock-based compensation charges on certain stock options.
- (2) During the year ended December 31, 1999, management decided to abandon our Memphis facility, resulting in a write-down of the unused facility totaling \$2.2 million, which included a reserve of \$0.8 million for future net lease costs. During the year ended December 31, 2000, a month-to-month lease with a related party was terminated on a facility resulting in a write-off of \$0.4 million for the unamortized leasehold improvements related to the facility.
- (3) We discontinued all foreign operations in 1999. For details of the components of discontinued operations, see Note 5 of the consolidated financial statements contained elsewhere in this Annual Report. Because these operations were substantially shut down in 1999, we incurred no related ongoing losses during the years ended December 31, 2000 and 2001.
- (4) All periods have been adjusted for a 2.2-for-1 stock split on October 30, 2000.
- (5) EBITDA consists of income (loss) from continuing operations before interest, income taxes, depreciation and amortization. Adjusted EBITDA is defined as EBITDA adjusted to exclude stock-based compensation charges and write-down of unused facilities. EBITDA and adjusted EBITDA should not be considered as measures of financial performance under generally accepted accounting principles (GAAP). Items excluded from EBITDA and adjusted EBITDA are significant components in understanding and assessing financial performance. We present EBITDA and adjusted EBITDA which are non-GAAP measures, to enhance the understanding of our operating results. EBITDA and adjusted EBITDA should not be considered in isolation or as alternatives to net income, cash flows generated by operations, investing or financing activities, or other financial statement data presented in the consolidated financial statements as indicators of financial performance or liquidity. Because EBITDA and adjusted EBITDA are not measurements determined in accordance with GAAP and are thus susceptible to varying calculations, EBITDA and adjusted EBITDA as presented may not be comparable to other similarly titled measures of other companies.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion of our financial condition and results of operations should be read in conjunction with our selected consolidated financial data and the consolidated financial statements and related notes included elsewhere in this Annual Report. This section includes forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by forward-looking information due to factors discussed under "Risk Factors," "Business" and elsewhere in this Annual Report.

For purposes of the following discussion, adjusted EBITDA (earnings before interest, income taxes, depreciation and amortization) is defined as EBITDA adjusted to exclude stock-based compensation charges and the write-down of unused facilities. For a complete definition of EBITDA, please see footnote 5 under "Selected Consolidated Financial Data."

Overview

We are a leading research-based clinical laboratory predominantly focused on developing and performing esoteric clinical laboratory tests, which we refer to as assays. We offer what we believe is the most comprehensive menu of esoteric assays in the industry, many of which have been developed through our internal research and development efforts. Following a business evaluation of the testing menu at the end of 2001 and the resultant elimination of certain low-volume services, the menu currently consists of more than 3,200 esoteric assays. Esoteric assays are complex, comprehensive or unique tests used to diagnose, evaluate and monitor patients. These assays are often performed on sophisticated instruments by highly skilled personnel and are therefore offered by a limited number of clinical laboratories.

We have grown rapidly in recent years. For the three years ended December 31, 2001, our net revenue grew at a compounded annual growth rate of 16%. This growth has resulted from our focus on expanding our hospital business via expansion of our sales and marketing forces, our investment in information technology, and our aggressive efforts to improve operating efficiencies and resultant turnaround time. In addition, we have supplemented this core growth with the acquisition of BBI Clinical Laboratories. We do not believe, however, that this past performance is necessarily indicative of future financial results. See "Risk Factors" for a discussion of some of the risks and uncertainties which may cause our results and performance to be materially different from our past performance.

We believe that our typical esoteric assay is priced at approximately twice that of a routine test. Our assays also have higher costs than routine tests due to the necessity of specialized laboratory instruments and highly skilled laboratory personnel. If we are successful in the expansion of our hospital customer base, and as we obtain or renew large customer or group purchasing organization contracts, our average price per assay will decrease as hospital esoteric referral testing is at lower average pricing and as large contracts typically incorporate volume discounts.

Since 1997, we have made significant investments in our business to expand sales and marketing capabilities and develop information technology and process automation. As part of our strategy to increase our penetration of the hospital market, we have grown our sales force to more than 60 persons at December 31, 2001 from 33 at December 31, 1997. We have spent more than \$7 million since 1998 to develop our customer-focused information technology suite of products. Since 1998, we have invested more than \$2 million in process automation, which we expect will increase our assay capacity and throughput, and reduce our cost of services.

R&D spending has averaged \$2.2 million per year since 1999. In 1999, we refocused our R&D efforts on the efficient introduction of new assays with significant potential for growth and higher average selling prices, many of these in molecular diagnostics. Molecular diagnostic assays represented

approximately 38% of our net revenue for the year ended December 31, 2001. We have also increased our efforts to license technologies developed by third parties that complement our internal R&D objectives. To continue growing our business, we intend to increase our overall level of R&D spending, including an accelerated pursuit of licensing arrangements.

Prior to 1997, our revenues were heavily dependent on national clinical laboratories. In 1997, we refocused our sales and marketing efforts to increase our penetration of the hospital market. One of our primary strategies has been to align ourselves with hospitals by not competing with them for the routine tests that represent a valuable source of revenue. As a result, the proportion of our net revenue from hospitals has increased. Net revenue from hospital customers as a percentage of total net revenue increased to approximately 56% for the year ended December 31, 2001 from 32.5% for the year ended December 31, 1997.

Since 1997, we have achieved consistent net revenue growth despite the substantial reduction of business from a significant independent laboratory customer, SmithKline Beecham Clinical Laboratories, or SmithKline Labs. SmithKline Labs business reduction resulted in an annualized net revenue reduction of approximately \$10 million in 1997 and approximately \$13 million in 1998.

As part of our continuing management development and succession planning program, on November 9, 2001, we announced that James B. Peter, M.D., Ph.D., had elected to step down from his position as Chief Executive Officer upon the completion of a search for his successor. An executive search firm has been retained and meetings with initial candidates have begun. Once a new Chief Executive Officer has been selected, Dr. Peter will remain as Chairman of the Board of Directors and will devote his efforts to our scientific initiatives and long-term strategy development.

Critical Accounting Policies

Revenue Recognition

Revenue is recognized as services are rendered upon completion of the testing process for a specific customer order for which we have no future performance obligation to the customer, the customer is obligated to pay and the fees are non-refundable. Our revenue recognition policies are in compliance with Securities and Exchange Commission Staff Accounting Bulletin No. 101.

Services are provided to certain patients covered by various third-party payor programs including Medicare and Medicaid. Billings for services under third-party payor programs are included in net revenue net of allowances for differences between the amounts billed and estimated receipts under such programs. Adjustments to the estimated payment amounts based on final settlement with the third-party payor programs are recorded upon settlement.

Expense Recognition

Expenses are recognized as incurred and are generally classified between cost of services and selling, general and administrative expenses. Components of cost of services include salaries and employee benefits, research and development costs, supplies and reagents, courier costs, depreciation of laboratory equipment and leasehold improvements. Selling, general and administrative expenses include salaries and employee benefits, sales and marketing, information technology, insurance and bad debt expense.

Stock-Based Compensation Charges

Stock-based compensation charges represent the difference between the exercise price of options granted, or the price of stock sold to employees and directors, and the deemed fair value of our common stock on the date of grant or sale in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. In the case of options, we recognize this compensation charge

over the vesting periods of the options using an accelerated amortization methodology in accordance with Financial Accounting Standards Board Interpretation No. 28. For purposes of the period-to-period comparisons included in "Results of Operations," selling, general and administration expenses exclude these stock-based compensation charges, which are reflected as a separate line item.

We have recorded deferred stock-based compensation related to unvested stock options granted to employees and directors. Based on the number of outstanding options granted as of December 31, 2001, we expect to amortize approximately \$726,000 of deferred stock-based compensation in future periods. We expect to amortize this deferred stock-based compensation approximately as follows: \$510,000 during 2002, \$188,000 during 2003, and \$28,000 during 2004. We anticipate that the exercise price of stock options granted after the calendar year of 2000 will be at the reported market price of our common stock, and therefore no deferred stock-based compensation will result from these grants.

Discontinued Operations

In fiscal year 1995, we began operating internationally by providing routine laboratory services and kit manufacturing to create revenue growth. In August 1999, we implemented a plan to discontinue all of our foreign operations, due to continued losses incurred with these foreign operations. We have no further obligations nor any plans to fund any additional losses of these foreign operations. For details of the components of discontinued operations, see Note 5 of the consolidated financial statements contained elsewhere in this Annual Report. Since these operations were substantially shut down in 1999, we incurred no related ongoing losses during the years ended December 31, 2000 and 2001.

Results of Operations

The following table sets forth the percentage of net revenue represented by certain items in our consolidated statements of operations.

	Years Ended December 31,		
	1999	2000	2001
Net revenue	100.0%	100.0%	100.0%
Cost of services	57.5	56.7	57.1
Selling, general and administrative (exclusive of stock-based compensation charges)	36.0	32.2	31.7
Operating income	2.6	10.2	10.6
Income from continuing operations before income taxes	1.4	9.6	12.5
Income from continuing operations	0.7	5.7	7.5
Loss from discontinued operations	(1.5)	—	—
Net income (loss)	(0.9)	5.7	7.5

Year Ended December 31, 2001 Compared with Year Ended December 31, 2000

Net Revenue

Net revenue increased approximately \$22.0 million, or 14.3%, to \$175.2 million for the year ended December 31, 2001 from \$153.2 million for the year ended December 31, 2000. Revenue grew as a direct result of increased accession volumes, which increased nearly 19% to more than 3.1 million assays for the year 2001 as compared to 2.6 million assays for the year 2000, offset partially by a decline in average selling prices. This accession growth came primarily from our existing business, increasing approximately 17% during the year as compared to the comparable prior year period. The accession volumes resulting from the acquisition of BBI Clinical Laboratories on February 20, 2001 accounted for nearly two percentage points of growth. Average selling prices for the year of 2001 declined approximately 4% as compared to the prior year of 2000. This reduction in average selling

prices is reflective of test mix changes resulting from our growing hospital customer base, pricing reductions in contract renewals, and the impact on test mix in September and October 2001 due to the events of September 11. Revenues from our hospital clients grew to approximately 56% of total net revenues for the year ended December 31, 2001 as compared to approximately 51% for the year ended December 31, 2000 as a direct result of our continued sales focus towards hospital customers.

Cost of Services

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased approximately \$13.1 million, or 15.1%, to \$100.0 million for the year ended December 31, 2001 from \$86.9 million for the comparable prior year period. This increase is directly attributed to the increase in assay volume and the costs associated with the acquisition of the clinical operations of BBI Clinical Laboratories in first quarter 2001. During the year, we maintained redundant operations as we transitioned the clinical operations of BBI Clinical Laboratories to our Santa Monica facilities. The transition of laboratory operations was completed during the third quarter of 2001. As a percentage of net revenue, cost of services increased to 57.1% for the year ended December 31, 2001 from 56.7% for the comparable prior year period. This decline is reflective of the additional costs associated with the BBI Clinical Laboratories acquisition offset partially by the improved efficiencies provided by the ongoing automation of our laboratory operations and the economies of scale realized by processing significantly higher assay volume.

Selling, General and Administrative Expenses (Exclusive of Stock-Based Compensation Charges)

Selling, general and administrative expenses (S,G&A) increased approximately \$6.3 million, or 12.9%, to \$55.6 million for the year ended December 31, 2001 from \$49.3 million for the prior year period. Selling, marketing and related expenses accounted for approximately \$2.7 million of this growth in S,G&A resulting from increased revenues and servicing a larger customer base. The acquisition of BBI Clinical Laboratories added more than \$1.6 million to S,G&A, which includes approximately \$400,000 of certain charges associated with the acquisition and approximately \$392,000 recorded for amortization of intangible assets during the year of 2001. Approximately \$1.5 million was due to increasing our corporate infrastructure to support our business growth and to meet the requirements of being a public company. Expansion of our customer related offerings of DataPassportMD™ and the beta testing of our Outreach Express™ contributed nearly \$1.0 million of incremental S,G&A. As a percentage of revenue, selling, general and administrative expenses decreased to 31.7% for year 2001 as compared to 32.2% for the comparable prior year period.

Stock-Based Compensation Charges

Stock-based compensation charges were \$1.1 million for both the years ended December 31, 2001 and 2000. These charges are related to the amortization of deferred stock compensation.

Write-Down of Unused Facilities

A property lease between the Company and a partnership in which the Company's Chairman of the Board and Chief Executive Officer, Dr. James B. Peter, was both a direct and indirect owner was terminated on September 1, 2000 on which date the Company had a balance of approximately \$369,000 in unamortized leasehold improvements for this property. A loss for this amount was recognized on September 1, 2000. No additional losses were recorded during 2001.

Interest (Income) Expense, Net

Net interest income increased to approximately \$3.5 million for the year ended December 31, 2001 as compared to net interest expense of approximately \$940,000 for the year ended December 31, 2000.

The increase in interest income is the result of investments being made with the proceeds from our initial public offering held in December 2000 as funds have been invested in money market, short-term and long-term investments. The decrease in interest expense is due to the reduction of debt in December 2000 paid by proceeds from our initial public offering.

Provision for Income Taxes

Provision for income taxes was \$8.9 million for the year ended December 31, 2001 as compared to \$6.1 million for the comparable prior year period. Our effective income tax rate declined slightly to 40.4% for the year ended December 31, 2001 from 41.1% for the year ended December 31, 2000. The effective tax rate decline is a result of tax planning reviews and initiatives.

Net Income

Net income increased by \$4.4 million, or 50.8%, to approximately \$13.1 million for the year ended December 31, 2001 from approximately \$8.7 million for the comparable prior year period. The increase is due primarily to an increase in operating income resulting from higher assay volume, efficiencies provided by ongoing automation of assays, and interest income recognized on the investment of funds from our initial public offering. As a percentage of net revenue, net income increased to 7.5% for the year ended December 31, 2001 as compared to 5.7% for the comparable prior year period.

EBITDA and Adjusted EBITDA

EBITDA increased by approximately \$3.9 million, or 18.1%, to \$25.5 million for the year ended December 31, 2001 from \$21.6 million for the comparable prior year period. As a percentage of net revenue, EBITDA increased to 14.5% for the year ended December 31, 2001 from 14.1% for the comparable prior year period. These results reflect the efficiencies provided by ongoing automation of assays, economies of scale associated with processing significantly higher assay volume partially offset by us maintaining redundant operations as we transitioned the clinical operations of BBI Clinical Laboratories to our Santa Monica facilities. Adjusting EBITDA for the non-cash expense related to stock-based compensation charges, adjusted EBITDA increased by approximately \$3.5 million, or 15.2%, to \$26.6 million for the year ended December 31, 2001 from \$23.1 million for the comparable prior year period. As a percentage of net revenue, adjusted EBITDA increased to 15.2% for the year ended December 31, 2001 from 15.0% for the comparable prior year period.

Year Ended December 31, 2000 Compared with Year Ended December 31, 1999

Net Revenue

Net revenue increased \$23.1 million, or 17.8%, to \$153.2 million for the year ended December 31, 2000 from \$130.1 million for the comparable prior year period. This growth came from increased testing volume, as overall assays increased by approximately 18% in 2000, exceeding 2.6 million assays in 2000. Our continued strategy of concentrating our sales force toward hospital customers has resulted in an increase in net revenues from that customer segment of approximately \$18.0 million in 2000. The balance of the net revenue growth of approximately \$5 million has come from independent laboratories, including Unilab. There was a modest decline in revenue from direct physician customers, primarily due to a concentrated effort to eliminate unprofitable accounts.

Cost of Services

Cost of services increased \$12.1 million, or 16.1%, to \$86.9 million for the year ended December 31, 2000 from \$74.8 million for the comparable prior year period. This increase is directly attributed to the increase in assay volume during the same period. As a percentage of net revenue, cost of services decreased to 56.7% for the year ended December 31, 2000 from 57.5% for the comparable

prior year period. The decrease reflects the economies of scale realized by processing significantly higher assay volume and efficiencies provided by the ongoing automation of our laboratory operations.

Selling, General and Administrative Expenses (Exclusive of Stock-Based Compensation Charges)

Selling, general and administrative expenses increased \$2.4 million, or 5.1%, to \$49.3 million for the year ended December 31, 2000 from \$46.9 million for the prior year-end. This growth came primarily from increased provisions for bad debts and sales and marketing expenses, which resulted from increased revenues and a growth in third party payors. This resulted in a decline in selling, general and administrative expenses as a percentage of net revenue, decreasing from 36.0% in 1999 to 32.2% for the year ended December 31, 2000.

Stock-Based Compensation Charges

Stock-based compensation charges decreased by \$1.7 million to \$1.1 million for the year ended December 31, 2000 from \$2.8 million for the comparable prior year period. The charge in the year ended December 31, 1999 included \$0.3 million related to a sale of stock to management and \$2.4 million related to stock options granted in February 1999. For the year ended December 31, 2000, variable stock-based compensation charges included \$0.1 million related to certain stock options for the period from July 1, 2000 through their dates of exercise in September 2000 and \$0.9 million related to amortization of deferred stock compensation.

Write-Down of Unused Facilities

Prior to SmithKline Labs substantially reducing its level of business with us, we had committed to lease and improve a building in Memphis, Tennessee, primarily to process assays for certain large independent laboratory customers. Subsequently, management decided in the second quarter of 1999 not to use the Memphis facility, resulting in a write-down of the facility totaling \$2.2 million, which included a reserve of \$0.8 million for future net lease costs. For more information concerning this write-down, see Note 6 of the consolidated financial statements appearing elsewhere in this Annual Report.

We terminated a facility lease in Santa Monica, California with Santa Monica Properties, a company owned by our Chairman and Chief Executive Officer, Dr. James Peter, effective September 1, 2000. A write-down of approximately \$0.4 million for the unamortized leasehold improvements to this facility was recorded in the third quarter of 2000.

Interest (Income) Expense, Net

Net interest expense decreased \$0.7 million, or 42.6%, to \$0.9 million for the year ended December 31, 2000 from \$1.6 million for the comparable prior year period. The decrease is due primarily to the reduction of our bank borrowings as a result of favorable cash flows from improved earnings. In December 2000, the outstanding revolving and term loans totaling approximately \$9.2 million were paid by proceeds from our initial public offering.

Provision for Income Taxes

Provision for income taxes was \$6.1 million for the year ended December 31, 2000 as compared to \$0.9 million for the comparable prior year period. We had an effective income tax rate for continuing operations of 41.1% for the year ended December 31, 2000. For the year ended December 31, 1999, the effective income tax rate for continuing operations was 52.0%, which was affected by expenses incurred in connection with our sale of stock to members of management in that period which were not deductible for income tax purposes.

Loss from Discontinued Operations

Loss from discontinued operations was \$2.0 million for the year ended December 31, 1999. We discontinued all of our foreign operations in 1999 and have no further obligations nor plans to fund any additional losses of these foreign operations. No further losses from discontinued operations were incurred during the year ended December 31, 2000.

Net Income (Loss)

Net income increased by \$9.8 million to \$8.7 million for the year ended December 31, 2000 from a net loss of \$1.1 million for the comparable prior year period. The increase is due primarily to increased operating income resulting from higher assay volume and efficiencies provided by ongoing automation of assays. The comparable 1999 period also contained charges in excess of current year charges of \$1.7 million for stock-based compensation, \$1.8 million for a write-down of unused facilities and \$2.0 million, net of income tax benefit, for discontinued operations.

EBITDA and Adjusted EBITDA

EBITDA increased by approximately \$12.8 million, or 145.5%, to \$21.6 million for the year ended December 31, 2000 from \$8.8 million for the comparable prior year period. As a percentage of net revenue, EBITDA increased to 14.1% for the year ended December 31, 2000 from 6.8% for the comparable prior year period. Adjusted EBITDA increased by \$9.2 million, or 66.4%, to \$23.1 million for the year ended December 31, 2000 from \$13.9 million for the comparable prior year period. As a percentage of net revenue, adjusted EBITDA increased to 15.0% for the year ended December 31, 2000 from 10.7% for the comparable prior year period. These results reflect economies of scale associated with processing significantly higher assay volume and efficiencies provided by ongoing automation of assays.

Liquidity and Capital Resources

Our working capital was \$58.7 million at December 31, 2001 as compared to \$88.8 million at December 31, 2000. After using approximately \$9.2 million of funds received from our initial public offering to reduce our outstanding revolving and term loans in the fourth quarter of 2000, the remaining \$73.4 million of funds were reflected as cash and cash equivalents at December 31, 2000. During 2001, a portion of these funds were invested in short-term and long-term investments as part of a strategy to improve interest income. As of December 31, 2001, \$37.4 million of these proceeds have been invested in long-term investments, and account for the reduction of working capital.

Net cash provided by operating activities was \$19.5 million for the year ended December 31, 2001 as compared to \$15.5 million for the prior year period. The \$4.0 million improvement was primarily due to our improved operating performance as income from operations increased by \$4.4 million, our improved management of account receivable slightly decreasing in 2001 as compared to a \$6.0 million increase in 2000, offset in part by reductions in accounts payable, income taxes payable, and other current liabilities.

Net cash used in investing activities reached \$82.5 million for the year ended December 31, 2001, up \$76.5 million from \$6.0 million for the prior year period. During the year 2001, we repositioned a portion of our cash and cash equivalents to short-term and long-term investments. These investments, accounting for \$59.6 million, are in high-grade instruments and commercial paper and will provide a better net after tax yield on our funds. Major uses of cash were \$9.1 million to acquire BBI Clinical Laboratories, \$8.7 million to acquire land in Valencia, California for our new facility, and \$5.1 million spent for capital expenditures to expand our information technology platform and laboratory automation and equipment.

Net cash provided by financing activities was \$2.6 million for the year ended December 31, 2001 as compared to \$65.4 million for the prior year period. Financing activities for the year of 2001 were the receipt of funds from the purchase of common stock by employees through our Employee Stock Purchase Plan and the exercise of stock options. In 2000, net cash provided by financing activities were the receipt of funds from our initial public offering offset by cash used for the repayment of outstanding bank debt in December 2000.

We expect that existing cash and cash equivalents, short-term investments, and our current credit facility along with funds generated from operations will be sufficient to fund our operations, meet our capital requirements to support our growth, and allow strategic technology licensing and acquisitions for the next year. The construction of our new facility will be financed by an independent third party and, upon completion, the facility will be leased back to us.

Inflation

Inflation was not a material factor in either revenue or operating expenses during the past three fiscal years ended December 31, 1999, 2000, and 2001.

Subsequent Events

In June and October, 2001, we underwent unannounced inspections by the California Department of Health Services (CDHS) representing both the State of California and acting as agent of the federal Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). As a result, we were cited by CDHS with 20 deficiencies under California law and CLIA-88. A separate statement indicating 12 overlapping deficiencies under CLIA-88 was issued by CMS in February 2002 based upon the same inspections. CDHS and CMS have indicated that if we fail to correct a total of six of the deficiencies, relating primarily to personnel licensing and the enforcement of regulatory requirements, we could face monetary and other penalties, up to and including revocation of our CLIA-88 license. We submitted a response and corrective action plan to CDHS in December 2001 in response to the CDHS statement of deficiencies. A more detailed response and corrective action plan was submitted to CMS in February 2002 in response to the CMS statement of deficiencies. By letter dated February 28, 2002, CDHS determined that the December 2001 submission did not constitute a credible allegation of compliance. CDHS and CMS are currently reviewing the February 2002 submission.

On February 13, 2002, Beckman Coulter, Inc. and Specialty announced a cross-licensing agreement to collaborate on the development of novel multi-analyte assays based on Beckman Coulter's new Progressive MicroArray platform. Multi-analyte assays combine multiple testing analyses in a single testing process.

On February 26, 2002, Zyomyx, Inc. and Specialty announced an agreement to collaborate on the application of the Zyomyx Protein Profiling Biochip™ technology for clinical diagnostics. As part of the collaboration, the two companies will pursue the identification of new disease marker patterns by re-analyzing archived clinical specimen using the protein chip technology. The two companies have an agreed structure whereby they share in the revenues generated by any potential assay or diagnostic kit resulting from the collaboration.

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board issued SFAS No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets" effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill will no longer be amortized but will be subject to annual impairment tests in accordance with the statements. Other intangible assets will continue to be amortized over their useful lives. The Company will apply the new rules on accounting

for goodwill and other intangible assets beginning in the first quarter of 2002. Application of the non-amortization provisions of the statement is not expected to have a material effect on the Company's financial statements. The Company will perform the first of the required impairment tests of goodwill as of January 1, 2002 and does not anticipate that any impairment will be identified.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

At any time, fluctuations in interest rates could effect interest earnings on our cash and cash equivalents and interest expense on our existing line of credit. We believe that the effect, if any, of reasonably possible near term changes in interest rates on our financial position, results of operations, and cash flows would not be material. Currently, we do not hedge these interest rate exposures. The primary objective of our investment activities is to preserve capital. We have not used derivative financial instruments in our investment portfolio.

At December 31, 2001, our holdings, which had an original maturity date of less than 90 days, were classified as cash and cash equivalents on our consolidated balance sheet. At December 31, 2001, we had cash and cash equivalents of \$15.2 million, which had a weighted average yield of 2.41% per annum. At December 31, 2001, our short-term investment balance of \$22.5 million, consisting of commercial paper and corporate bonds with maturity dates over 90 days and less than one year, had a weighted average yield per annum of 4.34% and an average of 34.78 days until maturity. At December 31, 2001, our long-term investment balance of \$37.4 million consisted of corporate bonds and government securities with maturity dates beyond one year, had a weighted average yield per annum of 4.35%.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Specialty Laboratories, Inc. financial statements, schedules and supplementary data, as listed under Item 14, appear in a separate section of this Report beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

PART III.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this Item is included in the Proposal One: Elections of Directors, Management, and Section 16(a) Beneficial Ownership Reporting Compliance sections of our Proxy Statement to be filed in connection with our 2002 Annual Meeting of Shareholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information under the caption "Executive Compensation and Related Information," appearing in our Proxy Statement, is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information under the caption "Beneficial Ownership of Securities," appearing in our Proxy Statement, is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information under the heading "Certain Transactions," appearing in our Proxy Statement, is incorporated herein by reference.

PART IV.

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) Documents filed as part of this Report:

1. **Financial Statements.** The following financial statements, and related notes thereto, of Specialty Laboratories, Inc. and the Report of Independent Auditors are filed as part of this Form 10-K.

	<u>Page</u>
Report of Ernst & Young LLP, Independent Auditors	F-1
Consolidated Balance Sheets at December 31, 2000 and 2001	F-2
Consolidated Statements of Operations for each of the three years in the period ended December 31, 2001	F-3
Consolidated Statements of Shareholders' Equity for each of the three years in the period ended December 31, 2001	F-4
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2001	F-5
Notes to Consolidated Financial Statements	F-6

2. Schedule II—Valuation and Qualifying Accounts is included at Item 14(d) of this Annual Report.

All other Schedules for which provision is made in the applicable accounting regulations of the SEC are not required under the release instructions or are inapplicable and therefore, have been omitted.

3. **Exhibits.** The Exhibits filed as part of this Annual Report are listed in Item 14(c) of this Annual Report on Form 10-K.

(b) Reports on Form 8-K:

A Current Report, Form 8-K, was filed on February 27, 2001 with the Commission, by the Registrant, in connection with a press release dated February 20, 2001 reporting the acquisition of certain assets of BBI Clinical Laboratories, Inc., a Massachusetts corporation, for \$9,500,000 in cash.

A Current Report, Form 8-K, was filed on March 12, 2001 with the Commission, by the Registrant, in connection with a press release dated March 1, 2001 announcing the appointment of John C. Kane to its Board of Directors.

A Current Report, Form 8-K, was filed on March 16, 2001 with the Commission, by the Registrant, in connection with a press release dated March 15, 2001, announcing the signing of a three-year agreement with Novation.

A Current Report, Form 8-K, was filed on April 10, 2001 with the Commission, by the Registrant, in connection with a press release dated April 9, 2001 announcing the appointment of Nancy-Ann DeParle to its Board of Directors.

A Current Report, Form 8-K, was filed on June 12, 2001 with the Commission, by the Registrant, in connection with a press release dated May 24, 2001, announcing the signing of a three-year agreement with AmeriNet.

A Current Report, Form 8-K, was filed on June 28, 2001 with the Commission, by the Registrant, in connection with a press release dated June 21, 2001 announcing an agreement with Axis-Shield plc of Dundee, Scotland for exclusive U.S. rights to a new gene-based test for predisposition to osteoporosis.

A Current Report, Form 8-K, was filed on July 30, 2001 with the Commission, by the Registrant, in connection with a press release dated July 24, 2001 announcing the commercial availability of diagnostic tests for human leukemias that incorporate Epoch Biosciences' proprietary Minor Groove Binder (MGB) technology.

A Current Report, Form 8-K, was filed on August 1, 2001 with the Commission, by the Registrant, advising that Paul F. Beyer, President, Chief Operating Officer and Director of the Company has established a written plan to sell shares of the Company's common stock in accordance with Rule 10b5-1 of the Securities Exchange Act of 1934, as amended.

A Current Report, Form 8-K, was filed on September 12, 2001 with the Commission, by the Registrant, advising that Frank J. Spina, Chief Financial Officer has established a written plan to sell shares of the Company's common stock in accordance with Rule 10b5-1 of the Securities Exchange Act of 1934, as amended.

A Current Report, Form 8-K, was filed on November 13, 2001 with the Commission, by the Registrant, in connection with a press release dated November 9, 2001 announcing that James B. Peter, M.D., Ph.D., as part of an established succession plan, has elected to retire from his position as Chief Executive Officer upon the completion of a search for his successor.

(c) Exhibits.

The following exhibits are filed as part of, or are incorporated by reference in, this Report.

Number	Description
3.1**	Articles of Incorporation.
3.2**	Form of By-laws.
4.1**	Specimen Common Stock Certificate.
4.2	See Exhibits 3.1 and 3.2 for provisions of the Articles of Incorporation and By-laws of the Registrant defining the rights of holders of Common Stock of the Registrant.
10.1**††	2000 Stock Incentive Plan.
10.2**††	2000 Employee Stock Purchase Plan.
10.3**	Loan Agreement dated April 15, 1996 between Union Bank of California and Registrant, as amended and restated on April 7, 1997 and as amended on January 23, 1998, February 17, 1999 and August 30, 1999.
10.4**	Revolving Note dated August 30, 1999 in favor of Union Bank of California.
10.5**	Term Note dated February 17, 1999 in favor of Union Bank of California.
10.6**	Term Note dated January 23, 1998 in favor of Union Bank of California.
10.7**	Term Note dated April 7, 1997 in favor of Union Bank of California.
10.8**	Security Agreement dated April 3, 1996 between Union Bank of California and Registrant.
10.9**	Lease dated June 1996 between Howard Real Property Trust (lessor) and Registrant (lessee) for the property located at 1752-1756 Cloverfield, Santa Monica, California.
10.10**	License Agreement, undated, between Southern California Edison Company (Licensor) and Registrant (Licensee) regarding Santa Monica Service Center property.
10.11**	Lease dated January 26, 2000 between WDI Santa Monica LLC (Lessor) and Registrant (Lessee) for the property located at 1756 22nd Street, Santa Monica, California.
10.12**	Lease dated July 17, 1993 between Oscar & Ethel Salenger Trust (Landlord) and Registrant (Tenant) for the property located at 2211 Michigan Avenue, Santa Monica, California.
10.13A**†	Agreement dated August 26, 1996, as amended on October 23, 1998 and as amended on December 31, 1999 between Triple G Corporation and Registrant.
10.14**†	Agreement dated June 6, 1992, as amended on August 25, 1997 and as amended on January 1, 1997 between Roche Molecular Systems, Inc. and Registrant.
10.15**†	Homogeneous PCR Clinical Agreement dated October 5, 1999 between Roche Molecular Systems, Inc. and Registrant.
10.16A ^o †	Supplier Agreement, dated March 5, 2001, between Novation and Registrant.
10.17**+†	Group Purchasing Agreement effective as of July 15, 1998 between AmeriNet, Inc. and Registrant as amended.
10.18A**†	Laboratory Services Agreement effective as of March 1, 1999 between Joint Purchasing Corporation and Registrant.

Number	Description
10.19A**†	Agreement dated June 7, 2000 between Managed Health Care Associates and Registrant.
10.20**†	Shared Services Health Care letter of confirmation dated June 5, 2000.
10.21A**	Sublease dated July 9, 1996, as amended on March 9, 1998 between The Rand Corporation (sublandlord) and Registrant (subtenant) for the property located at 1620 20th Street, Santa Monica, California.
10.22**††	Employment Agreement dated September 1, 2000 between James B. Peter and Registrant.
10.23**††	Employment Agreement dated September 1, 2000 between Paul F. Beyer and Registrant.
10.24**††	Employment Agreement dated September 1, 2000 between John W. Littleton and Registrant.
10.25**††	Employment Agreement dated September 1, 2000 between Bart E. Thielen and Registrant.
10.26**††	Employment Agreement dated September 1, 2000 between Thomas E. England and Registrant.
10.27A**††	Employment Agreement dated October 12, 2000 between Frank J. Spina and Registrant.
10.28A**†	Purchase and License Agreement dated June 19, 2000 between Sequenom, Inc. and Registrant.
10.29A**†	Letter Agreement dated April 14, 2000 between Third Wave Technologies, Inc. and Registrant.
10.30A**†	Collaborative Research, Development and License Agreement dated May 9, 2000 between Epoch Biosciences, Inc. (formerly known as Epoch Pharmaceuticals, Inc.) and Registrant.
10.31A**†	License Agreement dated March 15, 2000 between Gen-Probe Incorporated and Registrant.
10.32A**†	Laboratory Services Agreement dated October 15, 1999 between Unilab Corporation and Registrant.
10.33‡	Asset Purchase Agreement among Registrant, Boston Biomedica, Inc. and BBI Clinical Laboratories, Inc.
10.34*†	Marketing Arrangement dated April 5, 2001 between Axis-Shield Diagnostics Limited and Registrant, as amended.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, Independent Auditors.

* This exhibit was previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2001 with the Securities & Exchange Commission on August 10, 2001 and is incorporated by reference herein.

** This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 (File No. 333-45588) under the same exhibit number, and is incorporated by reference herein.

- ‡ This exhibit was previously filed as an exhibit to the Company's Annual Report on Form 10-K for the period ended December 31, 2001 with the Securities & Exchange Commission on March 30, 2001 and is incorporated by reference herein.
- This exhibit was originally filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 under the same exhibit number and an amendment was filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2001 on May 15, 2001 under exhibit Number 10.1, and is incorporated herein by reference.
- + This exhibit was originally filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 under the same exhibit number and an amendment was filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2001 on August 10, 2001 under the same exhibit number, and is incorporated by reference herein.
- † Confidential treatment requested and received as to certain portions of this agreement.
- †† Indicates a management contract or compensatory arrangement.

(d) Financial Statement Schedule

Schedule II—Valuation and Qualifying Accounts
Specialty Laboratories, Inc.

<u>Description</u>	<u>Balance at Beginning of Period</u>	<u>Additions Charged to Costs and Expenses</u>	<u>(1) Deductions</u>	<u>Balance at End of Period</u>
		(amounts in thousands)		
Year ended December 31, 2001				
Allowance for bad debts:	\$4,031	\$6,833	\$8,036	\$2,828
Year ended December 31, 2000				
Allowance for bad debts:	\$4,017	\$5,040	\$5,026	\$4,031
Year ended December 31, 1999				
Allowance for bad debts:	\$1,806	\$4,308	\$2,097	\$4,017

(1) Uncollectible accounts written off, net of recoveries.

Report of Ernst & Young LLP, Independent Auditors

Board of Directors
Specialty Laboratories, Inc.

We have audited the accompanying consolidated balance sheets of Specialty Laboratories, Inc. as of December 31, 2000 and 2001, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2001. Our audits also include the financial statement schedule listed in the Index at Item 14(a)(2). These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Specialty Laboratories, Inc. as of December 31, 2000 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ ERNST & YOUNG

Los Angeles, California

January 30, 2002,

except for Note 14, as to which
the date is February 28, 2002

Specialty Laboratories, Inc.
Consolidated Balance Sheets
(Dollar amounts in thousands)

	December 31	
	2000	2001
Assets		
Current assets:		
Cash and cash equivalents	\$ 75,604	\$ 15,183
Short-term investments	—	22,491
Accounts receivable, less allowances for doubtful accounts of \$4,031 in 2000 and \$2,828 in 2001	32,775	33,783
Deferred income taxes	4,239	1,571
Inventory	1,623	2,711
Prepaid expenses and other assets	1,496	1,785
Total current assets	115,737	77,524
Property and equipment, net	19,891	27,095
Long-term investments	—	37,389
Deferred income taxes	2,863	1,051
Goodwill, net	—	5,655
Other assets	3,514	5,274
	<u>\$142,005</u>	<u>\$153,988</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 11,922	\$ 9,465
Accrued liabilities	10,388	8,206
Income taxes payable	4,638	1,117
Total current liabilities	26,948	18,788
Long-term liabilities	3,260	2,544
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, no par value:		
Authorized shares—10,000,000 in 2000 and 2001		
Issued and outstanding shares—none	—	—
Common stock, no par value:		
Authorized shares — 100,000,000		
Issued and outstanding shares—20,937,507 in 2000 and 21,473,886 in 2001 . .	89,824	96,056
Retained earnings	24,103	37,182
Deferred stock-based compensation	(2,130)	(726)
Accumulated other comprehensive income	—	144
Total shareholders' equity	111,797	132,656
	<u>\$142,005</u>	<u>\$153,988</u>

See accompanying notes.

Specialty Laboratories, Inc.
Consolidated Statements of Operations
(Dollar amounts in thousands except per share data)

	Year Ended December 31		
	1999	2000	2001
Net revenue	\$130,142	\$153,245	\$175,169
Costs and expenses:			
Costs of services	74,784	86,857	99,955
Selling, general and administrative (exclusive of stock-based compensation charges)	46,903	49,277	55,613
Stock-based compensation charges	2,818	1,073	1,103
Write-down of unused facilities	2,209	369	—
Total costs and expenses	126,714	137,576	156,671
Operating income	3,428	15,669	18,498
Interest income	(53)	(303)	(3,585)
Interest expense	1,692	1,243	134
Income from continuing operations before income taxes	1,789	14,729	21,949
Provision for income taxes	930	6,056	8,870
Income from continuing operations	859	8,673	13,079
Loss from discontinued operations, net of income tax benefits	(2,001)	—	—
Net income (loss)	<u>\$ (1,142)</u>	<u>\$ 8,673</u>	<u>\$ 13,079</u>
Income (loss) per share—basic:			
Continuing operations	\$.05	\$.54	\$.62
Discontinued operations	(.12)	—	—
Net income (loss)	<u>\$ (.07)</u>	<u>\$.54</u>	<u>\$.62</u>
Income (loss) per share—diluted:			
Continuing operations	\$.05	\$.49	\$.59
Discontinued operations	(.12)	—	—
Net income (loss)	<u>\$ (.07)</u>	<u>\$.49</u>	<u>\$.59</u>

See accompanying notes.

Specialty Laboratories, Inc.
Consolidated Statements of Shareholders' Equity

(Dollar amounts in thousands)

	Common Stock		Retained Earnings	Deferred Stock Compensation	Loan to Shareholder	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount					
Balance, January 1, 1999	15,839,560	\$ 607	\$16,883	\$ —	\$(150)	\$(387)	\$ 16,953
Proceeds from sale of shares to employees, plus related compensation charge of \$342	227,121	617	—	—	—	—	617
Compensation charge related to stock options vested at date of grant	—	1,751	—	—	—	—	1,751
Deferred compensation related to stock options	—	1,080	—	(1,080)	—	—	—
Amortization of deferred compensation	—	—	—	726	—	—	726
Purchase of 2% interest in Specialty Family Limited Partnership	—	—	(311)	—	—	—	(311)
Loan to shareholder	—	—	—	—	(700)	—	(700)
Comprehensive income (loss):							
Foreign currency translation adjustment	—	—	—	—	—	387	387
Net loss	—	—	(1,142)	—	—	—	(1,142)
Total comprehensive loss	—	—	—	—	—	—	(755)
Balance, December 31, 1999	16,066,681	4,055	15,430	(354)	(850)	—	18,281
Deferred compensation related to stock option grants, net of forfeitures	—	2,714	—	(2,714)	—	—	—
Amortization of deferred compensation	—	—	—	938	—	—	938
Proceeds from exercise of stock options	257,575	314	—	—	—	—	314
Variable stock-based compensation charges for certain stock options	—	134	—	—	—	—	134
Repayment of loan by shareholder	—	—	—	—	850	—	850
Shares received and cancelled upon redemption of interest in Specialty Family Limited Partnership	(1,136,749)	—	—	—	—	—	—
Proceeds from sale of common stock net of \$9,393 in related expenses	5,750,000	82,607	—	—	—	—	82,607
Net income	—	—	8,673	—	—	—	8,673
Balance, December 31, 2000	20,937,507	89,824	24,103	(2,130)	—	—	111,797
Forfeited options, net of stock option grants	—	(301)	—	301	—	—	—
Amortization of deferred compensation	—	—	—	1,103	—	—	1,103
Tax benefit from exercise of employee stock options	—	3,930	—	—	—	—	3,930
Proceeds from sale of stock to employees	536,379	2,603	—	—	—	—	2,603
Comprehensive income:							
Unrealized gain on investments, net of taxes of \$100	—	—	—	—	—	144	144
Net income	—	—	13,079	—	—	—	13,079
Total comprehensive income	—	—	—	—	—	—	—
Balance, December 31, 2001	21,473,886	\$96,056	\$37,182	\$(726)	—	\$ 144	\$132,656

See accompanying notes.

Specialty Laboratories, Inc.
Consolidated Statements of Cash Flows
(Dollar amounts in thousands)

	Year ended December 31		
	1999	2000	2001
Operating activities			
Income from continuing operations	\$ 859	\$ 8,673	\$ 13,079
Adjustments to reconcile income from continuing operations to net cash provided by continuing operating activities:			
Depreciation	5,409	5,951	6,587
Amortization	—	—	400
Tax benefits from exercise of employee stock options	—	—	3,930
Deferred income taxes	(2,503)	(686)	4,380
Stock-based compensation charges	2,818	1,073	1,103
Write-down of unused facility	2,209	369	—
Loss on disposals of property and equipment	29	25	10
Changes in assets and liabilities net of effects from purchase of BBICL:			
Accounts receivable, net	(4,635)	(6,000)	338
Inventory, prepaid expenses and other assets	(1,983)	(953)	(796)
Accounts payable	438	1,803	(3,105)
Accrued liabilities	(935)	1,322	(2,182)
Income taxes payable	92	3,340	(3,521)
Other long-term liabilities	1,517	547	(716)
Net cash provided by continuing operating activities	3,315	15,464	19,507
Investing activities			
Cash paid for acquisition of BBICL	—	—	(9,142)
Purchases of property and equipment	(3,712)	(5,967)	(13,754)
Proceeds from sales of property and equipment	16	2	1
Purchase of investments	—	—	(59,636)
Net cash used in investing activities	(3,696)	(5,965)	(82,531)
Financing activities			
Net change in revolving bank line of credit	2,315	(11,954)	—
Borrowings under bank term loans	—	6,186	—
Repayment of bank term loans	(1,636)	(12,614)	—
Repayment of loan by shareholder (loan to shareholder)	(700)	850	—
Purchase of interest in Specialty Family Limited Partnership	(311)	—	—
Proceeds from sale of common stock, net of expenses	—	82,607	—
Sale of common stock to employees	276	—	—
Proceeds from exercise of stock options	—	313	572
Sale of common stock to employees under Stock Purchase Plan	—	—	2,031
Net cash (used in) provided by financing activities	(56)	65,388	2,603
Discontinued operating activities			
Net investment in foreign affiliates	285	—	—
Net cash provided by discontinued operating activities	285	—	—
Net (decrease) increase in cash and cash equivalents	(152)	74,887	(60,421)
Cash and cash equivalents at beginning of year	869	717	75,604
Cash and cash equivalents at end of year	\$ 717	\$ 75,604	\$ 15,183
Supplemental disclosures of cash flow information:			
Cash paid for:			
Interest	\$ 1,448	\$ 1,293	\$ 178
Income taxes	\$ 2,044	\$ 3,562	\$ 4,126
Details of business acquired in purchase transaction:			
Fair value of assets acquired	\$ —	\$ —	\$ 9,790
Less liabilities assumed	—	—	648
Net cash paid for acquisition	\$ —	\$ —	\$ 9,142
Details of accumulated other comprehensive income:			
Change in investments	\$ —	\$ —	\$ 244
Less change in deferred income taxes	—	—	100
Change in shareholders' equity	\$ —	\$ —	\$ 144

See accompanying notes.

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements

December 31, 2001

(Dollar amounts in thousands, except per share data)

1. Summary of Significant Accounting Policies

Description of Business

Specialty Laboratories, Inc. (the Company) is a corporation that provides specialized laboratory-testing services to physicians, hospitals, and independent laboratories throughout the United States. The Company's continuing operations are in one reportable segment, the domestic medical laboratory industry.

Discontinued Operations

In August 1999, management of the Company began implementing a plan for the discontinuance of all of the Company's foreign operations, which were located in Southeastern Asia, India and Egypt. This plan contemplated the sale or abandonment of each foreign location in which the Company had operations or interests. See Note 5 for additional information on discontinued operations.

Principles of Consolidation and Basis of Presentation

The consolidated financial statements include the accounts of Specialty Laboratories, Inc. and its subsidiary, BVI Specialty Laboratories International, Ltd. (SLIL) (100% owned). All intercompany transactions have been eliminated in consolidation.

Common Stock Split

On February 5, 1999, the Board of Directors amended the Company's Articles of Incorporation to effect a 100 for 1 stock split of the shares of common stock, and to increase the authorized number of shares of common stock to 10,000,000. On October 30, 2000, the Company's Board of Directors further amended the Company's Articles of Incorporation to effect a 2.2 for 1 stock split and to increase the authorized number of shares of common stock to 100,000,000. All per share and common share amounts presented in these consolidated financial statements have been adjusted to reflect the stock splits.

Foreign Currency Translation

Balance sheet accounts of the discontinued foreign operations are translated at the current exchange rate as of the end of the accounting period. Income statement accounts are translated at average currency exchange rates. The Company's portion of the resulting translation adjustment is recorded as a component of accumulated other comprehensive income (loss) in shareholders' equity.

Cash and Cash Equivalents

The Company considers highly liquid debt securities with original maturities of 90 days or less to be cash equivalents.

Investments

All investments (which include U.S. government and corporate debt securities) are designated as available-for-sale. Accordingly, investments are carried at fair value and unrealized gains and losses, net

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
December 31, 2001
(Dollar amounts in thousands, except per share data)

1. Summary of Significant Accounting Policies (Continued)

of applicable income taxes, are recorded in shareholders' equity. Investments are classified as short-term or long-term based on their contractual maturity dates.

Accounts Receivable and Net Revenue

Accounts receivable and net revenue are recorded net of contractual allowances. The allowance for doubtful accounts represents an estimate of future credit losses.

Inventory

Inventory consists primarily of laboratory supplies and is stated at the lower of the average cost or market.

Property and Equipment

Property and equipment are stated at cost. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the respective assets as follows:

Professional equipment	5 - 10 years
Office furniture and equipment	5 - 10 years
Automotive equipment	3 - 5 years
Computer equipment	3 - 5 years
Software	3 years
Leasehold improvements	The lesser of life of asset or lease term

Goodwill and Intangible Assets

The Company allocates the excess of the purchase price over the fair value of the net assets acquired to goodwill and identifiable intangible assets. Identifiable intangible assets include customer lists. The Company amortizes goodwill and intangible assets evenly over periods of 20 and 10 years, respectively. Accumulated amortization totaled \$0 and \$400 at December 31, 2000 and 2001, respectively.

Long-lived Asset Impairment

The Company reviews long-lived assets for impairment when events or changes in business conditions indicate that their carrying value may not be recovered. The Company considers assets to be impaired and writes them down to fair value if expected associated cash flows are less than the carrying amounts. Fair value is the present value of the associated cash flows. The Company has determined that no long-lived assets are impaired at December 31, 2001.

Revenue Recognition

The Company recognizes revenue as services are rendered upon completion of the testing process for a specific customer order for which the Company has no future performance obligations to the

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
December 31, 2001
(Dollar amounts in thousands, except per share data)

1. Summary of Significant Accounting Policies (Continued)

customer, the customer is obligated to pay and the fees are non-refundable. This generally occurs when the assay result is reported to the customer. The Company's revenue recognition policies are in compliance with Securities and Exchange Commission Staff Accounting Bulletin No. 101.

Services are provided to certain patients covered by various third-party payor programs including Medicare and Medicaid. Billings for services under third-party payor programs are included in net revenue net of allowances for differences between the amounts billed and estimated receipts under such programs. Adjustments to the estimated payment amounts based on final settlement with the third-party payor programs are recorded upon settlement. In 1999, 2000 and 2001, 5.5%, 5.5% and 4.6%, respectively, of net revenue was reimbursed by Medicare or Medicaid programs.

Research and Development Expenditures

Research and development expenditures are expensed as incurred. The amounts charged to research and development expense were \$2,332, \$2,094 and \$2,266 in 1999, 2000 and 2001, respectively.

Concentrations of Credit Risk

The Company's concentration of credit risk with respect to accounts receivable is limited due to the large number of payors comprising its customer base which are spread across the United States. In addition, the Company maintains allowances for potential credit losses and such losses have been within management's expectations. The Company routinely assesses the financial strength of its customers and generally does not require collateral.

No customer accounted for over 10% of net revenue in 1999, 2000 or 2001.

Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities, and the reported amounts of revenues and expenses. The Company routinely estimates amounts to be recovered from third-party payors. Actual results could differ from those estimates.

Stock-Based Compensation

As permitted by Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS No. 123), the Company accounts for stock options granted to its employees and outside directors using the intrinsic value method. The Company's stock options have generally been granted with exercise prices below the fair value of the Company's common stock as estimated by the Company's management for financial reporting purposes. For stock option grants which were vested at date of grant, the difference between the exercise prices and such estimated fair values was charged to expense as of the date of grant. For stock options not vested at date of grant, the Company has recorded deferred stock compensation for the difference between their exercise prices

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
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(Dollar amounts in thousands, except per share data)

1. Summary of Significant Accounting Policies (Continued)

and such estimated fair values which is being amortized to expense over the stock options' vesting periods in accordance with Financial Accounting Standards Board (FASB) Interpretation No. 28.

For sales of the Company's common stock to employees at a price below such estimated fair value, the difference between the sales price and such estimated fair value was charged to expense as of the date of the sales.

All outstanding stock options granted by the Company prior to 1999 were canceled in 1999 and were concurrently replaced with newly granted stock options. The exercise price for certain of the newly granted options was lower than the exercise price of the canceled options. These "repriced" options were accounted for as "variable" options effective July 1, 2000 until their exercise in September 2000 in accordance with FASB Interpretation No. 44.

Income Taxes

The Company utilizes the liability method of accounting for income taxes as set forth in Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes." Under this method, deferred income taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using current tax rates and regulations.

Fair Value of Financial Instruments

The Company's financial instruments consist mainly of cash, cash equivalents, short-term investments, long-term investments, accounts receivable, accounts payable and its bank credit facility. The fair value of substantially all financial instruments of the Company approximates their carrying values in the aggregate due to the short-term nature of these instruments. The interest rates on borrowings under the Company's bank credit facilities are adjusted periodically to market rates.

The Company has not used any derivatives or other foreign currency hedging instruments and, accordingly, believes that Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities," has had no effect on the Company's financial statements.

Earnings Per Share

Basic earnings per share is computed by dividing net income by the weighted average number of common shares outstanding. Dilutive earnings per share is computed by dividing net income by the weighted average number of common shares outstanding plus potentially dilutive shares for the portion of the year they were outstanding. Potentially dilutive common shares result solely from outstanding stock options.

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
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(Dollar amounts in thousands, except per share data)

1. Summary of Significant Accounting Policies (Continued)

Basic and diluted earnings per share information was calculated based on the following weighted average shares:

	Year ended December 31		
	1999	2000	2001
Basic—weighted average shares	16,044,529	16,100,978	21,186,541
Dilutive effect of outstanding stock options . .	959,796	1,537,780	1,057,232
Diluted—weighted average shares	<u>17,004,325</u>	<u>17,638,758</u>	<u>22,243,773</u>

In accordance with Statement of Financial Accounting Standards No. 128, "Earnings per Share," the diluted weighted average number of shares for 1999 was used for computing income from operations, loss from discontinued operations and net loss per share even though the effect of including dilutive stock options is anti-dilutive to the loss per share amounts.

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board issued SFAS No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets" effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill will no longer be amortized but will be subject to annual impairment tests in accordance with Statement No.142. Other intangible assets will continue to be amortized over their useful lives. The Company will apply the new rules on accounting for goodwill and other intangible assets beginning in the first quarter of 2002. Application of the non-amortization provisions of the statement is not expected to have a material effect on the Company's financial statements. The Company will perform the first of the required impairment tests of goodwill as of January 1, 2002 and does not anticipate that any impairment will be identified.

Reclassifications

Certain prior year amounts were reclassified to conform to the current year presentation.

2. Acquisitions

On February 20, 2001, the Company acquired certain assets and liabilities of BBI Clinical Laboratories, Inc. (BBICL), a Massachusetts corporation, for \$9.5 million in cash. The purchase price was allocated to the assets acquired and liabilities assumed based on the estimated fair values as of the purchase closing date. The acquisition agreement provided for a reduction of the purchase price if certain performance measurements (i.e., asset delivery, client retention and accounts receivable collections) were not achieved. A subsequent evaluation of these performance measurements resulted in the return of \$358 by BBICL to the Company in December 2001. Of the \$9.1 million net purchase price, approximately \$5.9 million was allocated to goodwill and \$1.9 million was allocated to the customer list. The acquisition has been accounted for under the purchase method of accounting. The operating results of BBICL are included in the financial statements from the acquisition date.

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)

December 31, 2001

(Dollar amounts in thousands, except per share data)

2. Acquisitions (Continued)

The following unaudited pro forma information below presents the consolidated results of operations as if the BBICL acquisition occurred at the beginning of each period. Such unaudited pro forma information is based on historical financial information with respect to the acquisition and does not include operational or other changes that might have been effected by the Company.

	Year Ended December 31,	
	2000	2001
Net revenue	\$161,809	\$176,073
Net income	\$ 8,411	12,993
Basic earnings per common share	\$.52	\$.61
Diluted earnings per common share	\$.48	\$.58

3. Marketable Securities

The following tables summarize marketable securities as of December 31, 2001.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable Securities:				
U.S. government and agency	\$ 6,000	\$ 49	\$ (8)	\$ 6,041
Corporate debt and other securities ..	53,636	237	(34)	53,839
	<u>\$59,636</u>	<u>\$286</u>	<u>\$(42)</u>	<u>\$59,880</u>

	Amortized Cost	Fair Value
Due in one year or less	\$22,480	\$22,491
Due after one year through five years	37,156	37,389
	<u>\$59,636</u>	<u>\$59,880</u>

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
December 31, 2001
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4. Property and Equipment

Property and equipment consists of the following:

	<u>December 31</u>	
	<u>2000</u>	<u>2001</u>
Information technology equipment and systems	\$23,103	\$25,729
Professional equipment	9,464	11,134
Office furniture and equipment	4,095	4,199
Land	—	8,658
Leasehold improvements	7,962	8,768
Construction in progress	615	423
	<u>45,239</u>	<u>58,911</u>
Less accumulated depreciation and amortization	<u>(25,348)</u>	<u>(31,816)</u>
	<u>\$19,891</u>	<u>\$27,095</u>

5. Discontinued Foreign Operations

In fiscal year 1995, the Company started operating internationally by providing routine laboratory services and kit manufacturing as an avenue to create growth. In August 1999, the Company implemented a plan to discontinue all of its foreign operations, due to continued losses incurred with these operations.

A wholly owned subsidiary of the Company owns 60% of Specialty Laboratories Asia Private, Ltd. (SLA) which, in turn, owns 50% of Specialty Ranbaxy, Ltd. (SRL) and 50% of Specialty Medical Laboratories Sdn. Bhd. (SML). During the year ended December 31, 1999, management began implementing a plan to close down the operations of SLA and to dispose of its interests in SRL and SML. As of December 31, 1999, SLA was insolvent. Since the Company has no further obligations nor any plans to fund additional losses of SLA, SRL or SML, the Company has not recorded any additional losses beyond those previously recorded. In July 2000, provisional liquidators of SLA were appointed by an Order of Court in Singapore. See Note 14 for a description of litigation involving SLA.

In August 1999, the Company began to shut down its Egyptian operations. The net assets of the Egyptian operations were written down to zero, as no net proceeds were anticipated to be received from their disposal. The Company ceased all operations in Egypt prior to December 31, 1999.

The foreign operations each served customers in their local markets by providing routine medical laboratory and health screening services to physicians and corporations, respectively, and differ from the Company's continuing operations, which provide esoteric testing primarily to hospitals and routine laboratories. The operations in Singapore and Malaysia also manufactured routine testing kits for sale to third parties in Asia. Because these business activities differ significantly and were managed separately from the Company's esoteric medical laboratory services, the foreign operations collectively would qualify as a separate business segment of the Company.

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
December 31, 2001
(Dollar amounts in thousands, except per share data)

5. Discontinued Foreign Operations (Continued)

There was no income or loss from discontinued operations during the years ended December 31, 2000 and 2001.

Condensed results of operations for the Company's discontinued foreign operations for the year ended December 31, 1999 are as follows:

Net revenue	\$ 643
Operating costs and expenses	<u>(2,158)</u>
	(1,515)
Disposal of property and equipment	(1,984)
Minority interests	<u>174</u>
Loss before income tax benefits	(3,325)
Income tax benefits	<u>1,324</u>
Loss from discontinued operations	<u><u>\$(2,001)</u></u>

6. Write-Down of Unused Facility Costs

In 1997, the Company leased a building in Memphis, Tennessee, for a potential geographical expansion of its operations. Subsequently, in June 1999, the Company's management decided not to move into the Memphis facility and to sublease it to a third party. As a result, the costs of leasehold improvements related to the facility of \$1,335 and the estimated present value of the difference between the Company's lease obligation and the estimated sublease income, which amounted to \$874 were recognized as a loss in 1999. The accrual of estimated future lease costs was computed by calculating the present value of the remaining lease payments, offset by the present value of the estimated future sublease income assuming a sublease start date of November 2002, using a discount rate of 7%. During 2001, \$237 was charged against the liability, which had a balance of \$232 at December 31, 2001. The Company's accrual of estimated lease costs is subject to change based on future events. Any future adjustment to the accrual will be classified as a write-down of unused facility costs in the Company's consolidated statements of operations. The facility had not been subleased as of December 31, 2001.

Beginning in 1997, the Company leased on a month-to-month basis a property from a partnership in which the Company's Chairman of the Board and Chief Executive Officer is both a direct and indirect owner. The Company utilized a portion of the property and subleased the remainder. As a result of the Company's initial public offering, the lease between the Company and the partnership was terminated on September 1, 2000 on which date the Company had a balance of \$369 in unamortized leasehold improvements for this property. Accordingly, a loss was recognized for this amount as of September 1, 2000.

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
December 31, 2001
(Dollar amounts in thousands, except per share data)

7. Accrued and Long-Term Liabilities

Accrued liabilities consist of the following:

	December 31	
	2000	2001
Employee compensation related	\$ 7,052	\$6,199
Royalties	3,336	2,007
	<u>\$10,388</u>	<u>\$8,206</u>

The Company has various royalty agreements for technology licensed from third parties which require that royalty fees be paid based upon a percentage of net revenue derived from assays using the licensed technology. Royalty payments are generally made on a semiannual basis.

Long-term liabilities consist of the following:

	December 31	
	2000	2001
Deferred compensation	\$1,908	\$1,895
Annuity payments due to former employee	453	349
Non-current portion of accrued rent for unused facility	232	—
Non-current installment of software acquisition costs	600	300
Other	67	—
	<u>\$3,260</u>	<u>\$2,544</u>

8. Long-Term Debt

The Company has a bank loan agreement which provides for a revolving line of credit up to \$30 million subject to a borrowing base limitation of 75% of eligible accounts receivable. Borrowings are cross collateralized by substantially all of the Company's assets and contain certain restrictive covenants, including maintenance of certain levels of financial ratios. Borrowings under this agreement bear interest at LIBOR plus a defined rate and are payable on September 30, 2003.

An initial term loan was payable over a five-year period with monthly payments of principal of \$83 plus interest, and a maturity date of March 31, 2002. A subsequent term loan was payable over a five-year period with monthly payments of principal of \$80 plus interest, with a maturity date of February 1, 2004. A third term loan was made in February 2000 in the amount of \$6,186 which was used to reduce outstanding borrowings under the revolving line of credit, and was payable with monthly payments of principal of \$129 plus interest, with a maturity of January 1, 2004. In December 2000, the Company repaid all of the outstanding term revolving and term loans totaling \$9,234 with the proceeds from the initial public offering.

There were no amounts outstanding under the line of credit or term loans at December 31, 2000 and 2001.

Interest expense for 1999, 2000 and 2001 was \$1,692, \$1,243 and \$134, respectively.

Specialty Laboratories, Inc.

Notes to Consolidated Financial Statements (Continued)

December 31, 2001

(Dollar amounts in thousands, except per share data)

9. Profit Sharing Plan—401(k)

The Company maintains a defined contribution 401(k) profit sharing plan (the 401(k) Plan) covering all employees after minimum eligibility requirements have been met. In accordance with the 401(k) Plan, eligible employees may contribute up to 15% of their salaries to the 401(k) Plan. The Company will match the employee's contribution at 50 cents per dollar up to 6% of the employee's salary. Matching contributions by the Company to the 401(k) Plan amounted to \$515, \$633 and \$686 in 1999, 2000 and 2001, respectively. Profit sharing contributions to the 401(k) Plan are discretionary and no discretionary contributions were made during 1999, 2000 and 2001.

10. Deferred Compensation Program

The Company has a non-qualified deferred compensation program (the Program) for certain executives. Under the Program, employee-designated deferrals of salary are withheld by the Company. An amount equal to the withholding is "invested" at the direction of the employee, in a portfolio of phantom investments selected from the available investments under the Program, which are tracked by an administrator. With a portion of the withholding, the Company purchases life insurance policies on each of the participating executives with the Company named as beneficiary of the policies.

Deferred compensation, including gains and losses on phantom investments, amounted to \$1,908 and \$1,895 at December 31, 2000 and 2001, respectively, and is classified in long-term liabilities. The cash surrender value of the life insurance policies, which amounted to \$1,408 and \$1,638 at December 31, 2000 and 2001, respectively, is recorded in other assets.

11. Shareholders' Equity

Preferred Stock

During 2000, the Company's Board of Directors amended the Company's Articles of Incorporation to authorize 10,000,000 shares of no par value preferred stock. No shares of preferred stock have been issued.

Ownership of Common Stock

On August 15, 2000, the Specialty Family Limited Partnership (Partnership) redeemed the Company's interest in the Partnership in exchange for 1,136,749 shares of the Company's common stock, which were then canceled by the Company.

Initial Public Offering

On December 8, 2000, the Company completed the initial public offering of 5,000,000 shares of its common stock at a price of \$16.00 per share. The underwriters subsequently exercised their overallotment option by purchasing an additional 750,000 shares of the Company's common stock at a price of \$16.00 per share. After underwriters' discounts, commissions and expenses, the net proceeds of the offering and overallotment exercise to the Company were \$85,560. Other expenses of the offering aggregated \$2,953.

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
December 31, 2001
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11. Shareholders' Equity (Continued)

Stock Option Plans

During 1999, the Company's Board of Directors approved the 1999 Stock Option/Stock Issuance Plan (the 1999 Plan) as a comprehensive equity incentive program and granted 1,839,068 options to acquire shares of the Company common stock to certain employees and outside directors of the Company. Outstanding stock options previously granted were effectively cancelled and replaced with new options under the 1999 plan. The options granted have an exercise price of \$1.21 or \$1.23 per share and 1,108,171 of such options were vested at their date of grant.

As of January 1, 2000, the Company granted to certain employees of the Company 132,000 options to acquire shares of the Company's common stock at an exercise price of \$1.56 per share. As of July 1, 2000 the Company granted to certain employees of the Company 255,200 options to acquire shares of the Company's common stock at an exercise price of \$7.00 per share.

On September 5, 2000, the Company's Board of Directors adopted and the shareholders approved the 2000 Stock Incentive Plan (2000 Plan). The 2000 Plan became effective on the date the underwriting agreement for the initial public offering was signed. Under the 2000 Plan, 4,020,280 shares of the Company's common stock have been authorized for issuance, including shares currently reserved under the 1999 Plan.

As of December 1, 2000, the Company granted to certain employees of the Company 406,060 options to acquire shares of the Company's common stock at an exercise price of \$14.00 per share and 47,000 options to acquire shares of the Company's stock at \$16.00 per share.

During 2001, the Company granted to certain employees and members of the Board of Directors 458,300 options to acquire shares of the Company's common stock at an exercise prices between \$10.00 and \$37.95.

The balance of the above options granted vest 25% upon the first anniversary of an employee's employment (33% for the outside directors upon the first anniversary of service as a director) and thereafter ratably in equal monthly installments for the next 36 months (the next 24 months for outside directors). On an annual basis, outside directors can elect to utilize a portion of their annual compensation to acquire an option grant to acquire shares of the Company's common stock at an exercise price equal to one-third of the fair market value each January 1. Such options vest in equal monthly installments over a 12 month period. The options have a term of 10 years from the date of grant. The difference between the option exercise price and fair value of the Company's common stock was recorded as deferred stock-based compensation and is being amortized to expense over the vesting periods of the related stock options on an accelerated basis using the graded vesting method.

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
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11. Shareholders' Equity (Continued)

Changes in options outstanding for the periods indicated were as follows:

	Number of Options	Weighted Average Exercise Price	Range of Exercise Prices
Outstanding at December 31, 1998	147,400	\$ 1.56	\$ 1.23 - \$ 1.76
Options canceled and replaced	(147,400)	\$ 1.56	\$ 1.23 - \$ 1.76
Options granted	1,839,068	\$ 1.21	\$ 1.20 - \$ 1.23
Outstanding at December 31, 1999	1,839,068	\$ 1.21	\$ 1.21 - \$ 1.23
Options exercised	(251,573)	\$ 1.22	\$ 1.21 - \$ 1.23
Options canceled	(89,155)	\$ 1.21	\$ 1.21
Options forfeited	(31,768)	\$ 5.63	\$ 1.23 - \$ 7.00
Options granted	840,260	\$10.03	\$ 1.56 - \$16.00
Outstanding at December 31, 2000	2,306,832	\$ 5.60	\$ 1.21 - \$16.00
Options exercised	(388,361)	\$ 1.47	\$ 1.21 - \$ 7.00
Options forfeited	(184,084)	\$16.56	\$ 1.56 - \$29.30
Options granted	458,300	\$28.15	\$10.00 - \$37.95
Outstanding at December 31, 2001	2,192,687	\$ 8.84	\$ 1.21 - \$37.95
Options exercisable at December 31, 1999	1,437,834	\$ 1.21	\$ 1.21 - \$ 1.23
Options exercisable at December 31, 2000	1,413,887	\$ 1.22	\$ 1.21 - \$ 1.56
Options exercisable at December 31, 2001	1,309,654	\$ 2.44	\$ 1.21 - \$16.00

There were no options exercised, forfeited or expired during 1999. The weighted average remaining contractual life of outstanding options was 8.8 and 8.1 years at December 31, 2000 and 2001, respectively.

Pro forma net income, as required to be disclosed by SFAS No. 123, determined as if the Company had accounted for its employee stock options under the fair-value method of that Statement, is as follows:

	Year ended December 31		
	1999	2000	2001
Income from continuing operations:			
As reported	\$859	\$8,673	\$13,079
Pro forma	338	8,207	12,502
Basic income from continuing operations per share:			
As reported	\$.05	\$.54	\$.62
Pro forma02	.51	.59
Diluted income from continuing operations per share:			
As reported	\$.05	\$.49	\$.59
Pro forma02	.47	.56

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
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11. Shareholders' Equity (Continued)

These pro forma amounts may not be representative in future disclosures since the estimated fair value of stock options would be amortized to expense over the vesting period, and additional options may be granted in future years.

The fair value for these options was estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Year ended December 31		
	1999	2000	2001
Risk-free interest rates	6%	6%	5%
Expected dividend yields	0%	0%	0%
Weighted-average expected life of option	5 years	5 years	5 years
Expected stock price volatility based upon peer companies55	.66	.66

Stock-Based Compensation

In connection with the sales of common stock to certain employees and the granting of stock options to certain employees and the Company's outside directors on February 5, 1999, the amount of related compensation to be recognized was determined by the Company to be the difference between the stock purchase or option exercise price and the fair value of the Company's common stock at that date. For the common stock sales and the stock options which were vested as of their date of grant, the related compensation was expensed in full as of February 5, 1999. For the stock options which were not vested as of their date of grant, the related compensation was recorded as deferred stock compensation which is classified as a reduction of shareholders' equity and is being amortized to expense over the vesting periods of the related stock options.

Stock-based compensation charges were comprised of the following components:

	Year ended December 31		
	1999	2000	2001
Charged to expense on transaction date:			
Stock options vested at date of grant	\$1,751	\$ —	\$ —
Common stock sold to certain employees	342	—	—
Amortization of deferred stock compensation	725	939	1,103
Variable stock-based compensation charges	—	134	—
	<u>\$2,818</u>	<u>\$1,073</u>	<u>\$1,103</u>

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
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11. Shareholders' Equity (Continued)

The Company estimates that amortization of deferred stock-based compensation, based upon stock options granted and forfeited during the year ended December 31, 2001 in addition to stock options outstanding at December 31, 2001, will be approximately as follows:

<u>Year ending December 31</u>	
2002	\$510
2003	188
2004	28

Stock Purchase Plan

On September 5, 2000, the Company's Board of Directors adopted and the shareholders approved an Employee Stock Purchase Plan (Purchase Plan). The Purchase Plan became effective on the date the underwriting agreement for the offering was signed. Under the Purchase Plan, 330,000 shares of the Company's common stock were reserved for issue. The share reserve automatically increases on the first trading day of each January by 1% of the total number of shares of the Company's common stock outstanding on the last trading day of each preceding December. The increase in the share reserve is not to exceed 550,000 shares. The shares are available for purchase through overlapping offering periods with a maximum duration of 24 months. The initial offering period began the day the underwriting agreement for the offering was signed and ends in October 2002. Subsequent offering periods begin on the first business day in May and November of each year. Each offering period consists of a series of successive six-month purchasing intervals. Employee share purchases are funded through payroll deductions not to exceed 15% of earnings. The purchase price of shares at each purchase date is the lesser of 85% of the fair market value of the shares on the purchase date or 85% of the fair market value per share on the start date of the offering period. During 2001, 148,018 shares had been purchased under the Purchase Plan.

12. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial statement purposes and the amounts used for income tax purposes.

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
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(Dollar amounts in thousands, except per share data)

12. Income Taxes (Continued)

Significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31	
	2000	2001
Current deferred tax assets (liabilities):		
Allowances for doubtful accounts and contractual allowances . . .	\$2,484	\$1,202
State income taxes	557	(150)
Vacation accrual	374	319
Other compensation accruals	824	300
Tax effect of unrealized gain on investments	—	(100)
	<u>4,239</u>	<u>1,571</u>
Non-current deferred tax assets (liabilities):		
Stock option compensation	1,330	—
Depreciation expense	(203)	256
Amortization expense	—	(36)
Other compensation accruals	1,736	831
	<u>2,863</u>	<u>1,051</u>
Net deferred tax assets	<u>\$7,102</u>	<u>\$2,622</u>

There is no valuation allowance for deferred tax assets since the Company believes that it is more likely than not that the results of future operations will generate sufficient taxable income to realize the remaining deferred tax asset.

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
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12. Income Taxes (Continued)

The components of the provision (benefit) for income taxes are as follows:

	Year ended December 31		
	1999	2000	2001
Continuing operations:			
Current:			
Federal	\$ 2,569	\$ 7,709	\$ 3,437
State	864	1,592	1,053
	<u>3,433</u>	<u>9,301</u>	<u>4,490</u>
Deferred:			
Federal	(1,848)	(2,644)	3,509
State	(655)	(601)	871
	<u>(2,503)</u>	<u>(3,245)</u>	<u>4,380</u>
Total continuing operations	930	6,056	8,870
Discontinued:			
Current:			
Federal	(1,030)	—	—
State	(294)	—	—
	<u>(1,324)</u>	<u>—</u>	<u>—</u>
Deferred:			
Federal	—	—	—
State	—	—	—
	<u>—</u>	<u>—</u>	<u>—</u>
Total discontinued operations	<u>(1,324)</u>	<u>—</u>	<u>—</u>
	<u>\$ (394)</u>	<u>\$ 6,056</u>	<u>\$ 8,870</u>

A reconciliation of the federal statutory rate to the Company's effective tax rate for continuing operations is as follows:

	Year ended December 31		
	1999	2000	2001
Tax provision at federal statutory rate	34.0%	35.0%	35.0%
State and local taxes, net of federal benefit	7.2	5.8	5.7
Non-deductible expenses	10.4	.2	.3
Other4	.1	(.6)
Effective tax rate	<u>52.0%</u>	<u>41.1%</u>	<u>40.4%</u>

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Notes to Consolidated Financial Statements (Continued)
December 31, 2001

(Dollar amounts in thousands, except per share data)

13. Related Party Transactions

During 1996, the Company loaned the Peter Family Revocable Trust (Trust) \$150 without interest. During 1999, the Company loaned to the Trust an additional \$700 which bore interest at a rate of 9%, which was paid monthly. Both loans were repaid in March 2000.

14. Commitments and Contingencies

The Company leases certain facilities and equipment under capital and operating leases. Certain leases contain renewal and purchase options. Rental expense was approximately \$3,010, \$2,830 and \$3,579 for 1999, 2000 and 2001, respectively.

Through September 2000, the Company leased on a month-to-month basis a facility and parking lot from Santa Monica Properties Partnership (SMPP) which is owned by various shareholders of the Company. Total payments to SMPP were \$205 and \$136 for 1999 and 2000 respectively, and are included in the amounts of rent expense shown above.

Future minimum lease payments under noncancelable operating leases with initial terms of one year or more are as follows:

	<u>Memphis Property</u>	<u>All Others</u>	<u>Total</u>
Year ending:			
2002	\$ 262	\$2,883	\$3,145
2003	262	2,236	2,498
2004	262	540	802
2005	262	255	517
2006 and thereafter	461	—	461
Total minimum lease payments	<u>\$1,509</u>	<u>\$5,914</u>	<u>\$7,423</u>

Contingencies

A former employee of SLA has obtained a judgment of \$350 against SLA and a default judgment of \$1.95 million in a wrongful termination action against SLA filed in Singapore. The former employee has filed an action against SLA in California to attempt to collect on the Singapore judgment and has obtained a default judgment of \$2.5 million against SLA in California. The former employee has also served discovery upon the Company and certain of its directors and officers, has sought to compel these officers and directors to provide discovery. No overt allegations of any material liability have been made against the Company. The Company's management believes that any claim against the Company or its directors and officers in connection with these judgments, if made, would be without merit and the Company would vigorously defend such action.

A former officer filed an action in federal district court against the Company and two of its officers alleging violations of federal and state securities laws and other causes of action in connection with the sale of the Company's common stock by the former officer and the Company's application of its insider trading policy. The Company's motion to compel arbitration was granted. The matter has

Specialty Laboratories, Inc.
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14. Commitments and Contingencies (Continued)

been submitted to binding arbitration before a former federal judge. Management believes the claims to be without merit and will vigorously defend this action.

In June and October 2001, the Company underwent unannounced inspections by the California Department of Health Services (CDHS) representing both the state of California and acting as agent for the federal Centers for Medicare and Medicaid Services (CMS) under Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). As a result, the Company was cited by CDHS with 20 deficiencies under California law and CLIA-88. A separate statement indicating 12 overlapping deficiencies under CLIA-88 was issued by CMS in February 2002 based upon the same inspections. CDHS and CMS have indicated that if the Company fails to correct a total of six of the deficiencies, relating primarily to personnel licensing and the enforcement of regulatory requirements, the Company could face monetary and other penalties, up to and including revocation of the Company's CLIA-88 license. The Company submitted a response and corrective action plan to CDHS in December 2001 in response to the CDHS statement of deficiencies. A more detailed response and corrective action plan was submitted to CMS in February 2002 in response to the CMS statement of deficiencies. By letter dated February 28, 2002, CDHS determined that the December 2001 submission did not constitute a credible allegation of compliance. CDHS and CMS are currently reviewing the February 2002 submission.

The Company is from time to time subject to claims arising in the ordinary course of business. These claims have included assertions that the Company's assays infringe existing patents; however, none of the claimants have filed litigation against the Company. The Company intends to defend vigorously any such litigation that may arise and to assert all available defenses to allegations of patent infringement that would be available to the Company. In the opinion of management, the ultimate resolution of such proceedings will not have a material adverse effect on the financial position or operations or cash flows of the Company.

Commitments

In September and October 2000, the Company entered into employment agreements with five employees. The agreements with two of the employees, which provide in the aggregate for annual base salaries of \$886 provide that if the employees are terminated other than for cause or if they resign for good reason during the first five years of their contracts, the Company will pay their base salaries for a two-year period and their bonuses for a one-year period subsequent to their severance. The agreements with the other three employees, which provide in the aggregate for annual base salaries of approximately \$584 provide that if the employees are terminated for other than cause during the first three years of their contracts, the Company will pay their salaries for a one-year period subsequent to their severance. If any of the five employees are terminated for cause, no further payments are due to them under the contracts.

Specialty Laboratories, Inc.
Notes to Consolidated Financial Statements (Continued)
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15. Quarterly Financial Data (Unaudited)

<u>CY2001</u>	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Net revenue	\$43,821	\$45,158	\$42,842	\$43,348
Operating income	4,659	4,660	4,006	5,173
Income from continuing operations	3,403	3,246	2,912	3,518
Net income	3,403	3,246	2,912	3,518
Income per share—basic	0.16	0.15	0.14	0.16
Income per share—diluted	0.15	0.15	0.13	0.16
<u>CY2000</u>				
Net revenue	\$35,607	\$38,557	\$39,550	\$39,531
Operating income	3,453	4,466	4,350	3,400
Income from continuing operations	1,827	2,406	2,378	2,062
Net income	1,827	2,406	2,378	2,062
Income per share—basic	0.11	0.15	0.15	0.12
Income per share—diluted	0.10	0.14	0.14	0.11

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Santa Monica, State of California, on the 12th day of March, 2002.

SPECIALTY LABORATORIES, INC.

By: /s/ JAMES B. PETER

Name: James B. Peter

Title: *Chief Executive Officer and Chairman of
the Board of Directors*

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, the undersigned hereby constitute and appoint Paul F. Beyer and Frank J. Spina, and each of them, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite or necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed by the following persons in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ JAMES B. PETER</u> James B. Peter, M.D., Ph.D.	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 12, 2002
<u>/s/ PAUL F. BEYER</u> Paul F. Beyer	President, Chief Operating Officer and Director	March 12, 2002
<u>/s/ FRANK J. SPINA</u> Frank J. Spina	Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2002
<u>/s/ DEBORAH A. ESTES</u> Deborah A. Estes	Secretary and Director	March 12, 2002
<u>/s/ RICHARD E. BELLUZZO</u> Richard E. Belluzzo	Director	March 12, 2002

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ NANCY-ANN DEPARLE</u> Nancy-Ann DeParle	Director	March 12, 2002
<u>/s/ DOUGLAS S. HARRINGTON</u> Douglas S. Harrington, M.D.	Director	March 12, 2002
<u>/s/ JOHN C. KANE</u> John C. Kane	Director	March 12, 2002
<u>/s/ WILLIAM J. NYDAM</u> William J. Nydam	Director	March 12, 2002
<u>/s/ THOMAS R. TESTMAN</u> Thomas R. Testman	Director	March 12, 2002